INSTRUCTION MANUAL FOR THE COLLINS EAGLE
Flow-Based Pulmonary Laboratory

#7602008

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Caution
Federal law restricts this device to
sale by or on the order of a physician.

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THE FOREGOING WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES (EXCEPT TITLE) EXPRESSED OR IMPLIED, INCLUDING WARRANTY OF MERCHANTABILITY AND WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.

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SECTION ONE -- COLLINS EAGLE HARDWARE

Description

1. *Hardware* refers to the physical aspects of the Collins Eagle, which is a flow-based pulmonary system used to conduct certain tests directed by Collins PlusSQL 2000 software - spirometry, lung volumes, and diffusion testing.

2. The Eagle consists of a compact testing unit connected to a breathing valve mounted at the end of an articulated arm. The arm may be attached to the edge of a desktop or an optional cart may be used to house the entire system, including the computer, printer and monitor.

3. The breathing valve automates a variety of pulmonary function test procedures. Under the direction of the software, two balloons open and close in the valve, thereby directing gas/sample flow throughout the Eagle. A one-way demand valve attached to the breathing valve allows the patient to breathe in test gas as required by the test protocol. The Eagle is equipped with the microGA Multiple Channel Analyzer (MGA), which measures the fraction of CO_2 (carbon dioxide), CO (carbon monoxide), and CH_4 (methane) in each patient breath or in the calibration gas mixture during diffusion testing.

4. Spirometry measurements are made with the use of the pneumotach, referred to as the Collins GEMtach and located on the breathing valve. The patient breathes through the GEMtach, which is a device that measures flow across a flow-resistive element, in this case, the pneumotach screen. The inspired and expired flow readings are then integrated into volume readings with the aid of a computer.

7. The Eagle allows complete lung volume measurement by use of the Nitrogen (N_2) washout method. In the N_2 washout test, the patient breathes tidally from a tank containing 100% O_2 and exhales to room air. In the process, the gas analyzer monitors the declining concentration of N_2 in each breath, which is plotted and used in calculations to arrive at RV. The Eagle is equipped with an O_2 analyzer for arriving at lung volume measurements using the N_2 washout method.

8. Diffusion testing has been enhanced to provide results according to the Graham, Mink, and Cotton 3-equation method.* This method overcomes certain assumptions inherent in the Jones-Meade method, which is based on the Krogh equation. Use of the 3-equation method makes available the following parameters in the DL report:

    - e3_dlco
    - e3_ch4_wash_vol
    - e3_end_exp_vol
    - e3_f_deadspace

    For more details on this method, refer to the following text:

    * Graham BL, Mink JT, Cotton DJ
    "Implementing the three-equation method of measuring single-breath carbon monoxide diffusing capacity"
    Can Respir J 1996; 3(4):247-257.

9. The computer, keyboard, monitor and printer comprise the rest of the Eagle system. Refer to Section One of the PLUS 2000 manual for computer system requirements.

10. The Eagle may be integrated with the Collins BP^D Plethysmograph in order to add diffusion testing to the spirometry and lung volume testing functions of the BP^D.

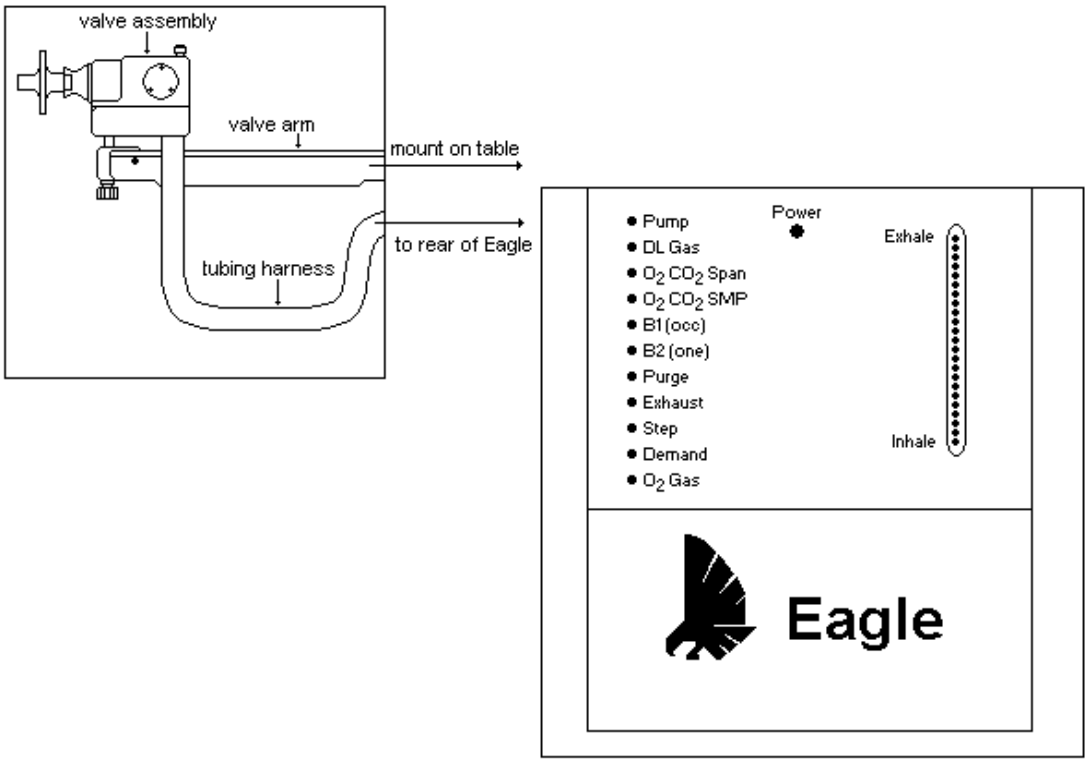


Figure 1-1. The Collins Eagle System – Tabletop Model

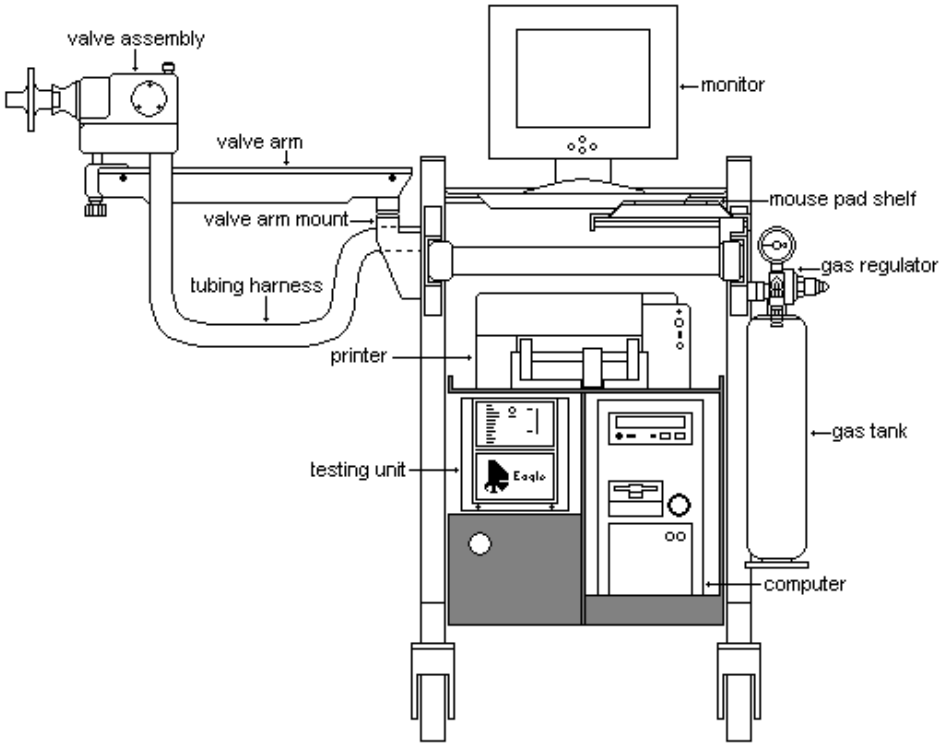


Figure 1-2. The Collins Eagle System – with Optional Cart

Manuals

There are two manuals for the system:

a. The **Eagle Hardware manual**, which you are now reading.
b. The **PLUS 2000 software manual.**

The **Eagle manual** describes system installation, testing setup, maintenance and troubleshooting.

The **PLUS 2000 manual** describes all other aspects of the software, including calibration, patient testing, configuration and reports.

Collins Eagle Technical Specifications

Dimensions	7 ½" X 17" X 7 ½" (19.2 cm X 43.6 cm X 19.2 cm)
Weight	21.1 lbs. (9.6 Kg)
Equipment Classification	Class I Continuous Use with Short-Time Loading Type B Applied Part Equipment not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE
Electrical Requirements:	115 - 240 VAC 50 - 60 Hz, 3.15 Amps
Fuse Type and Rating	Two fuses, each T2AL 250V
Cord Set	
Maximum voltage rating	250V
Maximum current rating	6A
Conductor size	18 AWG / 3 X 0.75 mm2
Cordage type	3-wire Thermoplastic (PVC) Jacket JTO or H05VVF30.75
Cord-set length	8 feet or 2.5 m.
	Conductors in power supply cords intended to be connected to the neutral conductor of the supply system shall be colored "light blue" as specified in IEC publication 227 (amendment no. 1) or in IEC publication 245. The equipment is a Class I device that requires the use of a 3-wire Class I cord-set. For Denmark it is extremely important that the Schuko CEE 7/7 plug not be used because it will mate with the Danish socket but it will not be grounded. This may result in serious safety hazards.
Operating Environment	Temperature, 13 to 46 ^{O}C (55 to 105 ^{O}F) Relative Humidity, 0% to 95%
Storage and Transportation Environment	Temperature, -40 to 70 ^{O}C (-40 to 158 ^{O}F) Humidity, 10% to 90% (non-condensing)
Type of Protection against Electric Shock	Class I Product – Equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution in that means are provided for the connection of the equipment to the protective earth conductor in the fixed wiring of the installation in such a way that accessible metal parts cannot become live in the event of failure of the basic insulation.
Degree of Protection against Electric Shock	Type B Applied Part – Equipment providing a particular degree of protection against electric shock, particularly regarding: • Allowable leakage current • Reliability of the protective earth connection (if present)
Degree of Application in Presence of Flammable Mixtures	Equipment not suitable for use in the presence of flammable mixtures

Gas Analysis Bench
(CO, CH_4, CO_2)

Type	Infrared (NDIR)
CO, CH_4 Range	0-3000 PPM
CO_2 Range	0-15%
Response	< 100 msec
Sample Rate	100 Hz
Accuracy	1%
Linearity	<1%
Noise	<1% Full Scale

Oxygen Analyzer

Type	Electrochemical
Range	0.1-100% O_2
Accuracy	1%
Response	80 ms

Pneumotach (Collins GEMtach)

Type of Pneumotach	Screen Type
Linearity	2%
Resistance	< 1.5 cm H_2O/L/sec
Accuracy	+/- 3%
Flow Range	+/- 15 L/sec

A/D Converter

Input	16 Bit
Resolution	300 µvolts

Calibration

Analyzers	Autocal of gains, delays, and response times under software control.
Volume	3-liter calibration syringe
Mouth Pressure	Water Manometer 0-10 cmH_2O

Hardware Options

Computers	Pentium Computer - Typical
Printers	Windows® 2000 Compatible Color Printer
Monitor	SVGA

Tests Performed

Spirometry
Lung Volumes:
- Single Breath DL_{CO}
- Nitrogen Washout

Diffusing Capacity (Single Breath DL_{CO})
Bronchoprovocation

Test Gases

Type	**Specifications**	**Fitting**
Oxygen	99.6% by volume	CGA #870
Lung Diffusion	0.3% CO, 0.3% CH_4, 21% O_2, Bal N_2 by volume	CGA #973
CPX Span	5% CO_2, 15% O_2, balance N_2 by volume	CGA #973

Safety Precautions

This section discusses certain safety precautions:

The Collins Eagle has been tested and certified to be compliant to UL2601-1 and CAN/CSA C22.2 NO. 601.1. Class I equipment electric shock protection is provided by 3-wire power cord earth ground and additional external earth ground as described. However, the following precautions must be observed for auxiliary equipment:

a. Use of a non-601 or non-Class II approved computer, connected to the system from outside the patient environment, requires external ground connection from Eagle to earth ground.

b. Use of a non-601 or non-Class II approved computer, connected to the system from within the patient environment, requires external ground connection from Eagle to earth ground.

And

An external ground connection from the computer to the ground.

Collins has provided the necessary grounding equipment and instructions with its systems.

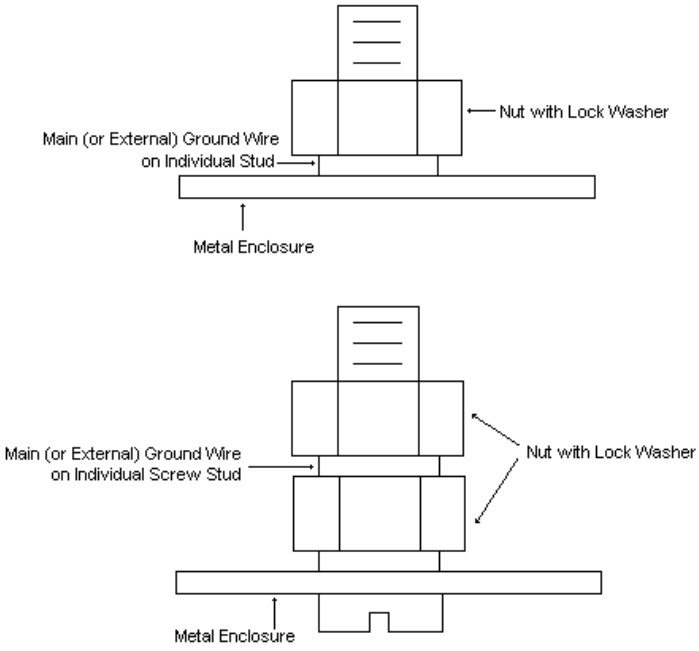


Figure 1-3. External Ground Configurations
--Reference Collins Ground Wire Kit Instructions #700887

c. The power cord for each component must be individually connected to a wall source.

d. Do not connect extension cords to the system.

e. Multiple portable socket outlets are not to be used.

f. Operate the Eagle system only when the power cords are plugged into "U" grounded outlets (3-holed outlets).

g. Unplug the power cords in the event that any servicing is required.

h. The computer, monitor, printer and the Eagle testing unit are components fit for use within the patient environment provided external grounding has been implemented per instructions.

i. The User/Operator must not touch any non-medical device (that is, any device other than the Eagle testing unit) and the patient at the same time.

j. The Eagle has been tested and meets the latest EMC requirements for immunity and emissions of IEC 60601-1-2:1998, Draft 2nd Ed. If for some reason you are having problems with interference, contact the Service Department at 800-635-3200. Examples of occurrences that could interfere with testing include: power supply transients, magnetic interference, mechanical interaction, vibration, thermal radiation and optical radiation.

k. Do not connect items that are not specified as part of the Eagle System.

l. Do not operate the Eagle or other system components on any voltage other than that specified.

m. When connecting non-medical equipment be sure that total leakage current of combined systems does not exceed the limit concerning combined systems stated in IEC 60601-1-1. Refer to the figure below for the leakage testing configuration. Leakage testing must be conducted by qualified personnel only.

n. All flammable materials must be kept away from the equipment and No Smoking signs must be prominently displayed in the testing area.

o. Oil and grease must be kept away from oxygen equipment.

p. Oxygen-approved regulators must be used for O_2 tanks.

q. The equipment is a Class I device that requires the use of a 3-wire Class I cord-set. For Denmark it is extremely important that the Schuko CEE 7/7 plug not be used because it will mate with the Danish socket but it will not be grounded. This may result in serious safety hazards.

r. The Eagle packaging is recyclable (corrugated cardboard, wooden pallet and plastic bubble wrap) in many locations. Otherwise, packaging can be disposed of through normal waste disposal methods according to local regulations. The accessories used are disposable at their respective ends-of-life as normal waste. This includes the filters, GEMtachs, breathing tubes and calibration syringe. The printed circuit boards can easily be removed from the interface and disposed of separately according to local guidelines concerning printed circuit boards.

s. Good hygiene practice when handling used filters and/or mouthpieces mandate not touching the parts that came into direct contact with the patient's mouth or aerosolized droplets from the patient's effort. Dispose of filters and mouthpieces as ordinary waste, or as specified by your institution.

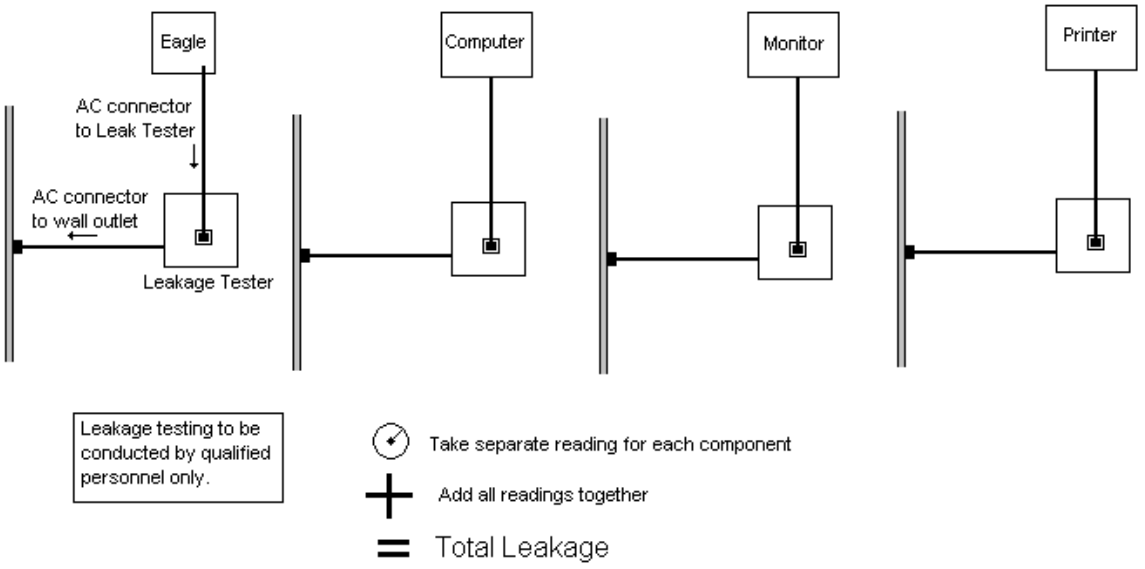


Figure 1-4. Leakage Testing Configuration

Labeling Glossary

WARNING statements identify conditions or practices that could result in personal injury or loss of life.

CAUTION statements identify conditions or practices that could result in damage to equipment.

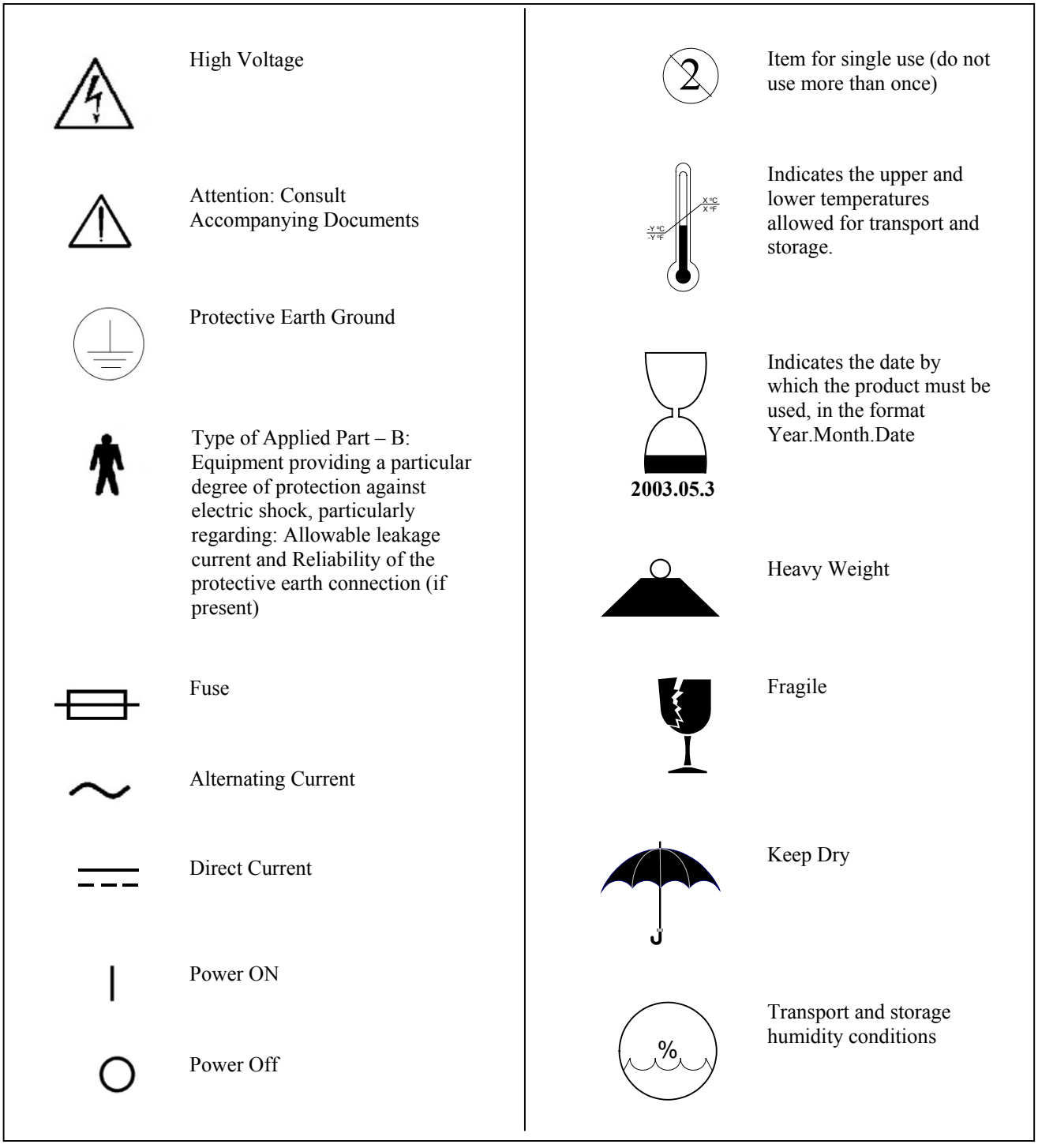

High Voltage
Attention: Consult Accompanying Documents
Protective Earth Ground
Type of Applied Part – B: Equipment providing a particular degree of protection against electric shock, particularly regarding: Allowable leakage current and Reliability of the protective earth connection (if present)
Fuse
Alternating Current
Direct Current
Power ON
Power Off
Item for single use (do not use more than once)
Indicates the upper and lower temperatures allowed for transport and storage.
Indicates the date by which the product must be used, in the format Year.Month.Date
2003.05.3
Heavy Weight
Fragile
Keep Dry
Transport and storage humidity conditions

Figure 1-5. Glossary of Common ISO Symbols

Installation

Preparation

1. This section describes how to prepare for installation, unpack and position the Eagle and related accessories. The cabling procedure follows this section.

2. Have the following in mind when preparing an area for system installation:

   a. Identify an area for location of the Eagle, computer, monitor, keyboard, mouse, and printer.

   b. If you will be using a table or the optional cart, verify that there is sufficient area, height, and placement to provide an optimum workflow between keyboard information entry, patient positioning, and patient traffic.

   c. Consider cable lengths, doorways, traffic areas, patient placement, and equipment usage.

   d. Discuss alternatives with your department head before setting up the equipment.

   e. If a situation requires additional materials (such as a worktable or movement of equipment within the department), start this process immediately to avoid prolonged installation delays.

Unpacking

1. The Eagle comes packaged in two boxes. One contains the Eagle body, identified by the serial number on the outside. The other box contains the parts and accessories.

2. Place the Eagle box on a level surface, such as a table, and open it from the top.

3. Remove the foam packaging pillow from the top of the Eagle.

4. Grasp the Eagle unit from the bottom, then carefully lift it up out of the box. Place it on a level surface.

5. Place the accessories box on a level surface and open it from the top. Carefully remove the contents, being sure to examine all packing materials for small parts before discarding.

6. Inspect all equipment for damage. Even though, before leaving the factory, all Collins instrumentation and related equipment have met strict mechanical and electrical quality control standards as of the date of manufacture, damage sometimes occurs during shipping. Should any damage be found, contact the Customer Service Manager at 800-635-3200 or your local distributor for further handling instructions.

7. Make sure all packing materials are removed from the boxes before any attempt is made to assemble or start up the equipment.

8. When unpacking, be sure to keep all equipment, accessories and cabling out of high traffic areas.

Moving the Eagle

The Eagle unit is small and easily carried by a single individual. To move the Eagle from one location to another, first make sure that all cables and power cords are unplugged and that they are kept free of the unit so as not to be damaged. Then carry it to another level surface, making sure to place it down gently.

Cable and Power Cord Connections

1. The Eagle system is installed by a Collins representative. However, at some point you may need to relocate or reload your system. For this purpose, the cabling and setup procedures are described below.

2. The following cabling instructions and accompanying diagram represent a sample cabling configuration. Keep in mind that depending on the computer configuration, yours may be different.

3. In addition to the Safety Precautions at the beginning of this section, observe the Caution Note below

CAUTION:

Whenever the system or parts of it are to be moved, make sure to disconnect the appropriate cables in order to avoid damaging them.

4. The first step is to connect all system components to the computer via the cables provided.

5. Plug the cable of the computer keyboard into the circular port reserved for it at the rear of the computer.

6. Plug the video monitor cable into the adapter reserved for the monitor on the rear of the computer. Secure the screws at both ends of this and all other connectors with a small screwdriver.

7. Plug one end of the printer cable into the appropriate connector on the printer. Plug the other end into the adapter reserved for the printer at the rear of the Computer.

8. Plug the rounded end of the USB cable into the connector at the bottom rear of the Eagle. Plug the flat end of the USB cable into the appropriate port at the rear of the computer.

9. Plug the appropriate end of the Eagle power cable into the receptacle at the rear of the Eagle, to the right of the USB cable.

10. Plug the power cords for the printer, monitor, and the Eagle into appropriate, individual wall outlets. Refer to *Safety*.

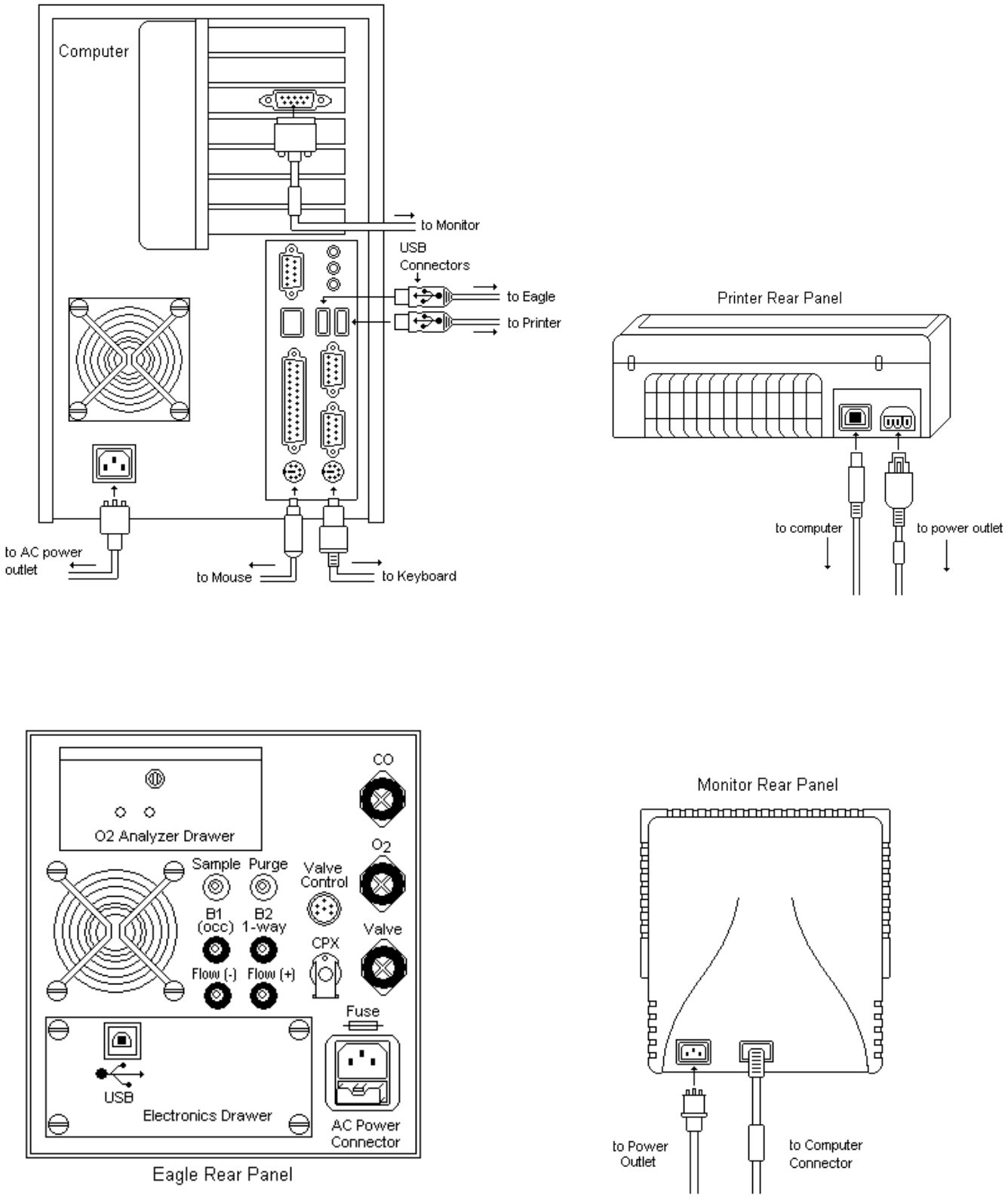


Figure 1-6. Eagle Cable and Power Connections

Preparing the Gas Tanks

1. The calibration/test gas tanks are connected to the rear of the Eagle. You will need to turn these tanks on when directed to by the test instructions. There are three gas tanks:

   CO - DL test gas (0.3% CO, 0.3% CH_4, 21% O_2, balance N_2)
   O_2 - 99.6% USP O_2 Gas tank (for lung volumes via Nitrogen Washout method)
   CPX Span – 5% CO_2, 15% O_2, balance N_2

   NOTE:
   In order to insure proper calibration of the Eagle, it is mandatory that these be certified calibration gasses.

2. The components associated with the gas tanks are as follows:

   Tank Stem: This is the metal stem at the top of the tank. When this stem is turned counterclockwise with a tank wrench, the full pressure of the tank is released. The regulator dial displays the full pressure of the gas coming out of the tank.

   Regulator: This is the assembly that mounts on top of the tank over the valve stem. Its function is to reduce and regulate the pressure coming out of the tank, as indicated by the dial, to a preset pressure. The Eagle tanks are preset at the factory at 50 psi.

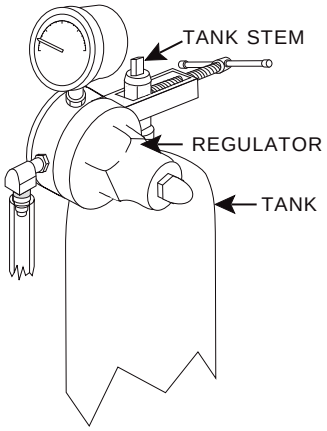


Figure 1-7. Gas Tank Components

3. Secure the appropriate regulator gauge on each cylinder. Indexing pins and holes on the regulators and cylinders ensure proper regulator-cylinder attachment so that they won't be mismatched.

4. Tighten the gauge to the cylinder by turning the T-handle on the regulator tankmount clockwise.

5. Attach the tubing leading from each regulator to its respective inlet at the rear of the Eagle (*DL (CO)*, *O_2* and *CPX Span* gas tank connectors; refer to Figure 1-7). Note that each tubing connection is different and is keyed so that the connections won't be mismatched.

   Each connection has a metal quick-release tab, either on the tubing end or on the Eagle inlet port, depending on the particular connector. Press down on the quick-release tab and, while holding the tab down, slide the tubing end into (or over, depending on the particular connector) the corresponding inlet port on the Eagle; then release the tab. Likewise, to remove the tubing, press down on the quick-release tab and slide the tubing end from the inlet port.

6. To open the gas cylinders, turn the regulator stems counterclockwise with a tank wrench. Then, if you have a needle valve, turn it 3 or 4 times counterclockwise. To close the cylinders, turn the needle valve fully clockwise; then turn the regulator stems clockwise with a tank wrench.

NOTE:

Over-tightening the regulator stems could cause damage to the cylinders. Therefore, do not use a long-handled wrench to tighten the stems; use only the tank wrench. Recommended torque is 35-inch lbs.

Eagle Tubing Connections

1. If you have not done so, attach the gas tanks to their respective inlets on the Eagle rear panel. Refer to *Preparing the Gas Tanks*, above.

2. The Valve tubing is encased in a harness. On the Valve end, each of these tubes is connected to tubing leading into the valve via color-coded fittings. Each of the opposite tubing ends must be connected to the appropriate fittings on the Eagle testing unit. Refer to the Figure below.

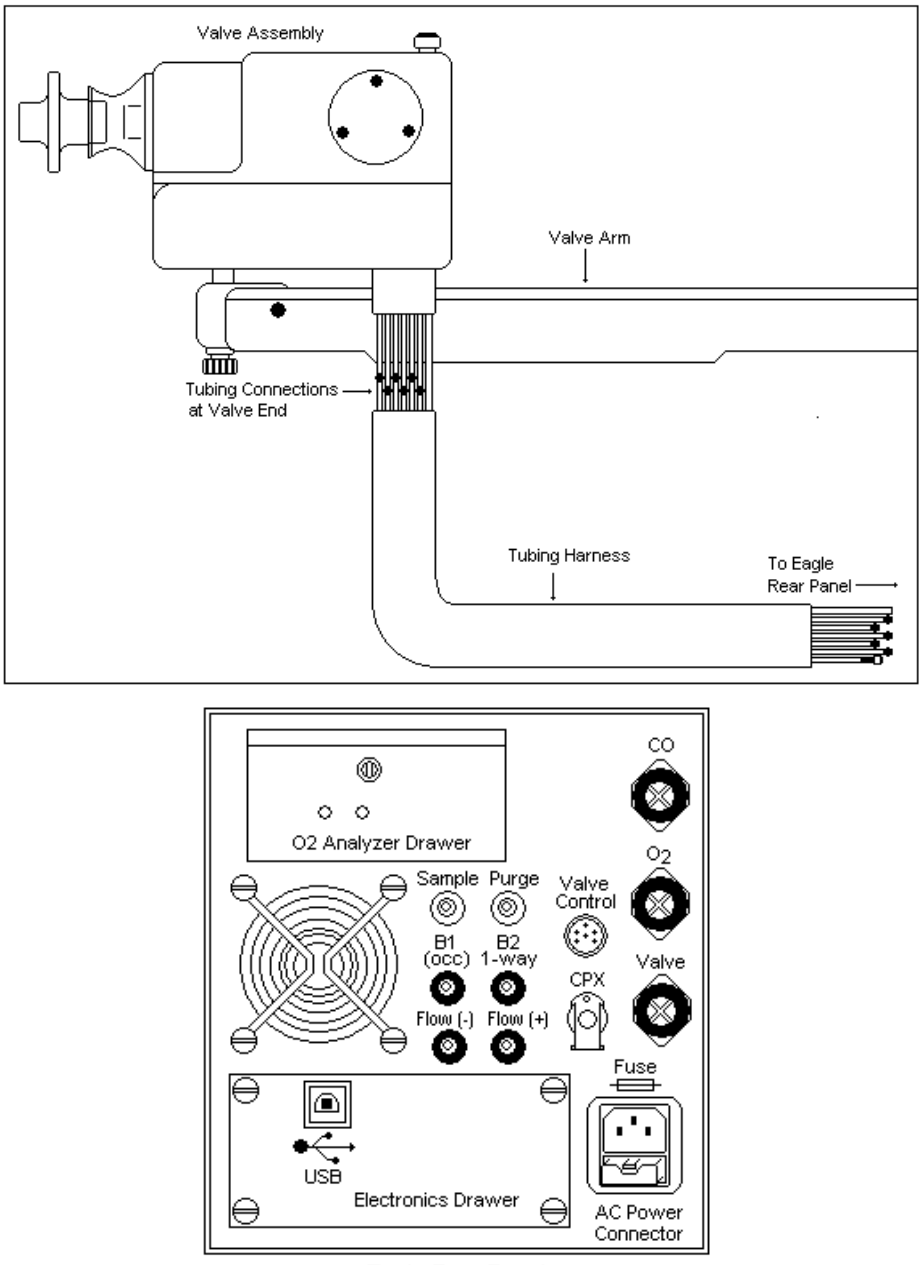


Figure 1-8. Eagle Valve and Rear Panel Connectors

3. Connect the electrical cable to the Valve Control port on the Eagle.

4. Attach the tubing leading from the Demand Valve (shown in Figure 1-9) to the connector labeled Valve at the rear of the Eagle. The Valve tubing has a plain end and the Eagle connector has a blue ring around it. Simply slide the tubing end into the connector until it is securely attached. To release the connection, press against the blue ring and pull the tubing out.

5. Attach the flow tubing with the red connector to the Flow (-) port on the rear of the Eagle (connector and port are color-coded).

6. Attach the flow tubing with the green connector to the Flow (+) port on the rear of the Eagle.

NOTE:

When connecting these and other Luer fittings, always give the fitting a $^{1}/_{2}$ turn counterclockwise before sliding it onto the connector. This will ensure that the tubing is tight.

7. Attach the Purge (black), B1(blue) and B2 (yellow) tubing to their respective color-coded ports on the Eagle.

8. The DL Sample line must be connected between the DL sample tubing leading from the Valve and the Sample connector on the Eagle. The Sample tubing (white connectors) consists of a Nafion (braided) end that is connected to the Valve tubing and a Teflon (clear plastic) end that is connected to the Eagle Sample connector via a hydrophobic filter. Refer to the Figure below. (See also *Maintenance -- Changing the DL Sample Line*.)

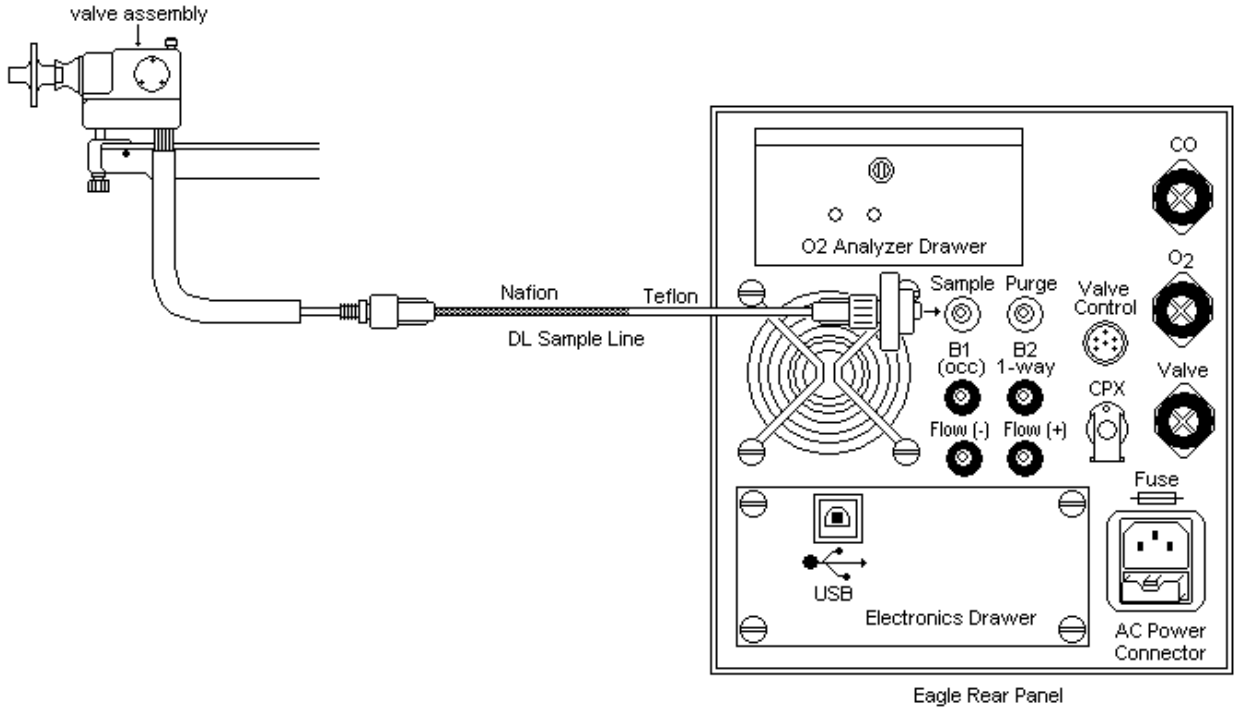


Figure 1-9. DL Sample Line Connections

Preparing the Breathing Valve

1. The arm holds the Breathing Valve, which is shown below. Insert the reduced end of the demand valve (end with O-ring) into the breathing valve.

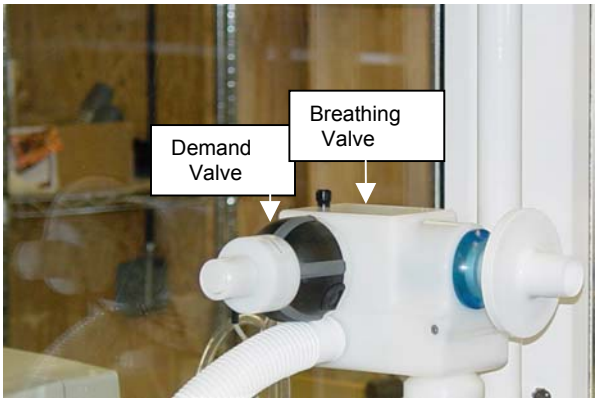


Figure 1-10. The Demand Valve Connected to the Breathing Valve

2. Slide the connecting end of the GEMtach into the patient port on the Breathing Valve.

3. Insert the reduced end of a DC-2 filter into the patient port on the GEMtach. If the patient has difficulty maintaining a tight seal on the DC-2, you may also attach the Collins Comfort Fit® mouthpiece to the patient end of the filter.

NOTE:

The Collins DC-2® filter is a low-resistance barrier filter designed for use in preventing patient saliva droplet contamination of pulmonary equipment, thereby preventing patient cross-contamination.

The Collins Comfort Fit® Mouthpiece is used to connect the patient comfortably and securely to the DC-2 filter on the breathing valve. A clean mouthpiece must be used for each patient.

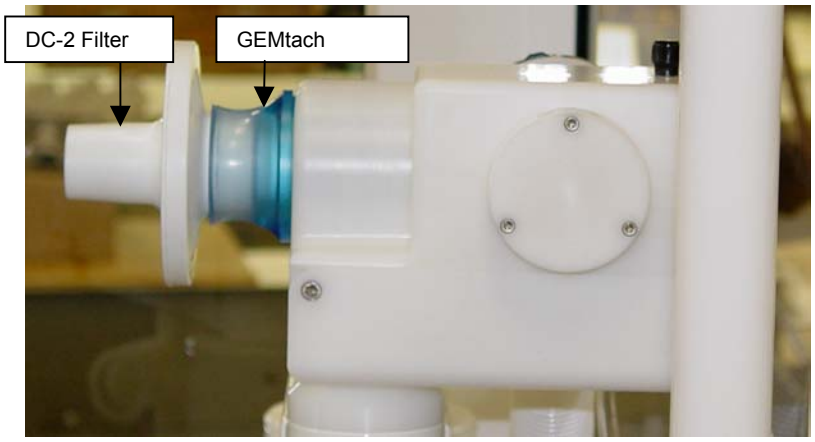


Figure 1-11. Attaching the GEMtach and the DC-2 Filter to the Breathing Valve

Powering up the System

1. Be sure to observe the Safety Precautions, which precede the Eagle Installation instructions.

2. Each system unit, that is, the Eagle, BP^D, monitor, printer, and computer, must be plugged into an individual isolated wall outlet. This requires that each component be powered up individually by turning on the power switch.

3. The Eagle power switch is located on the right side of the unit towards the front. To turn the power to the Eagle on, push this rocker switch to the I position. The green Power light on the front of the Eagle will be illuminated, signifying that it is energized.

4. Turn on each of the other system components according to their respective documentation.

5. The monitor will display a series of system data, followed by the Windows Desktop with the available applications.

6. Adjust the monitor screen for brightness and clarity according to the monitor documentation.

Components and Controls

Following is a list of each Eagle component and control for quick reference.

Analyzers

The Eagle analyzers are located internally and are used to analyze the gas content of patient breath samples.

O_2 Analyzer: This is a fuel cell-type analyzer, which measures the O_2 concentration in each patient breath or in the calibration gas during Nitrogen Washout testing. To replace, refer to *Maintenance*.

microGA Multiple Channel Analyzer: This analyzer measures the amount of CO_2, CO, and CH_4 in each patient breath or in the calibration gas during Diffusion testing.

Rear Panel

AC Power Cord: The power cord for the Eagle unit is located at the lower right corner of the rear panel. This cord must be plugged into a U-grounded outlet.

Cal Gas Inlet Ports (DL, O_2, CPX Span): The calibration gas from the tanks enters the Eagle system via these three ports. Each port is equipped with a color-coded, quick-disconnect or Luer fitting. To connect the calibration tanks, attach the tubes to their color-matched fittings.

Gas Outlet Port (Valve): Gas from inside the Eagle exits through this port to the demand valve through a length of tubing. Components inside the Eagle regulate which gas is released to the valve when called for by the software.

Sample: The gas sample produced during the DL test travels from the Breathing Valve to the gas analyzers inside the Eagle through this port (white) via a length of Nafion tubing.

NOTE:
The sample line tubing is of a specified length and must not be trimmed back if worn or damaged. Instead, replace the tube. The sample line is equipped with a filter at the sample input end, which must be changed periodically. Refer to *Maintenance* for details.

Purge: The gas sample produced during the DL test returns from the analyzers to the breathing valve through this port (black) and then is re-circulated through the system.

Flow Ports (Flow+ and Flow-): The Collins GEMtach is connected to these 2 ports (red for negative flow and green for positive flow) via the appropriate tubing.

Valve Electrical Connector (Valve Control): This connector provides power to the Breathing Valve.

Fuse: Located in a compartment below the power cord, two fuses provide protection to the Eagle electrical circuitry.

Electronics Drawer: This drawer, located at the bottom rear of the Eagle, contains the device's electronics on two printed circuit boards.

Cable Connector for Computer: At installation, a USB cable is attached between this connector and the appropriate connector at the rear of the computer. See *Installation -- Cable and Power Cord Connections*.

O_2 Analyzer Drawer: The O_2 Analyzer is located in this drawer. For directions in replacing an aging O_2 analyzer, refer to Section Two.

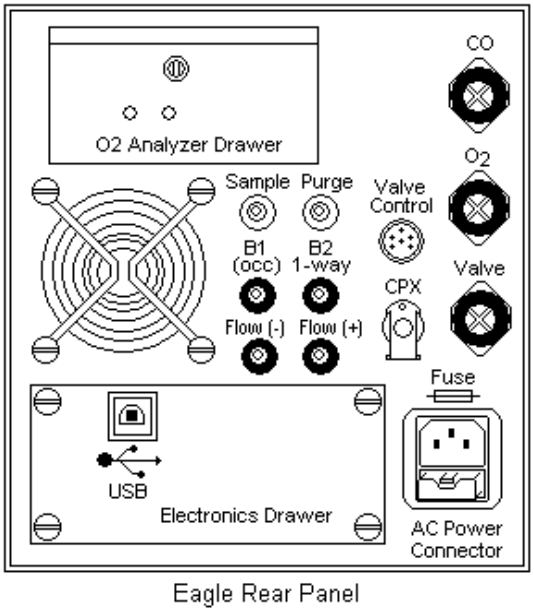


Figure 1-12. Eagle Rear Panel Components and Controls

Front Panel

The front panel consists of the LEDs that are illuminated during specific functions of the Eagle.

Power ON Light: When this LED is illuminated, the power to the Eagle is On.

Exhale/Inhale LED: Indicates when the GEMtach is detecting inhalation or exhalation and the relative magnitude of each breath.

Function Lights: When illuminated, indicate which circuits and components of the Eagle are activated.

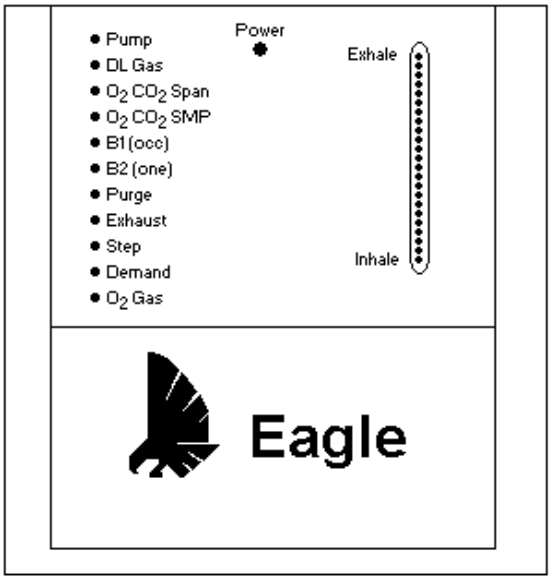


Figure 1-13. Eagle Front Panel Components and Controls

Breathing Valve and Accessories

Refer to *Description* and *Setting up the Breathing Valve* in this section for a description of these components.

SECTION TWO -- PERIODIC MAINTENANCE

WARNING:
Before performing any maintenance procedures, make sure the power to the Eagle system is off and all power cords are disconnected and that all gasses are disconnected.

Contacting Customer Support

The Eagle has no user internal serviceable parts. Therefore, for issues not covered in Maintenance, or if you are having problems with your system, contact Collins Medical personnel at:

Collins Medical, Inc,
220 Wood Road
Braintree, MA 02184

Phone 800-635-3200
or
781-843-0610 and ask for the Customer Support Services Department

FAX: 781-843-4024

...or your local distributor

Routine Cleaning of the Eagle Cover and External Components

Frequency: Annually

1. Turn off the power to the Eagle by moving the rocker switch at the right side of the unit to the O position.

2. Remove the power cord from the inlet connector.

3. All external components of the system, including the system cover, used within the patient environment, may be disinfected by wiping the surfaces with a 70% isopropyl alcohol solution. DO NOT get the solution on or near the AC power inlet connector.

4. Plug in the power cord.

5. Turn on the power to the Eagle by moving the rocker switch to the I position.

6. Refer to *Installation* to verify correct system start-up.

7. If your system does not start up correctly, contact Collins Customer Support Services at the addresses or telephone numbers listed above.

Replacing Fuses

Frequency: As needed

1. **Shut off the Eagle power! Remove the power cord!**

2. The fuses are located in a protruding holder below the AC power connector. Remove the holder by pressing down on the tab in the middle and pulling on the holder until it pops out of the unit. It may be necessary to use a pair of needle nose pliers to do this if you find the tab difficult to depress.

3. Pull the fuses from the holder and examine the fine wire element inside each. If a fuse has blown, this element will be separated.

4. Replace each blown fuse in the holder with a T2AL 250V fuse.

5. Slide the fuse holder back into the unit until you hear it click into place.

NOTE:
If the fuses blow again, contact Collins Medical, Inc.

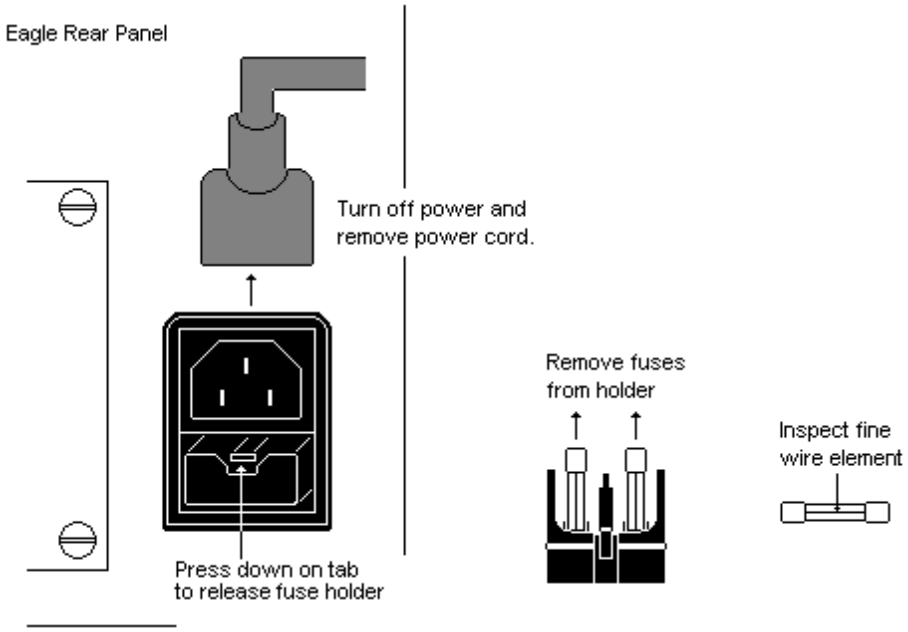


Figure 2-1. Replacing the Fuses

Replacing the DL Sample Line and Filter

Frequency: The DL sample line should be replaced every four months.
The filter should be replaced once a year.

1. The sample line has a Nafion end (braided) that attaches to the Valve tubing and a short Teflon end (smooth) that attaches to the Eagle Sample port via the filter.

2. To change the sample line, disconnect the Nafion end from the Valve tubing by turning the fitting counterclockwise.

3. Unscrew the Teflon end of the sample line from the filter on the Eagle by turning the fitting counterclockwise.

4. Screw the Teflon end of the new sample line to the filter by turning the fitting clockwise.

5. Connect the Nafion end of the new sample line to the Valve tubing, turning the fitting clockwise. This completes changing the sample line.

6. To change just the filter, unscrew the filter from the Eagle Sample port.

7. Unscrew the sample line from the filter and replace the filter with a new one.

8. Attach the free end of the filter to the Sample port on the Eagle.

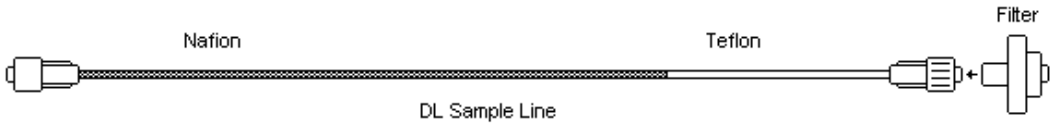


Figure 2-2. Connecting the DL Sample Line to the Filter

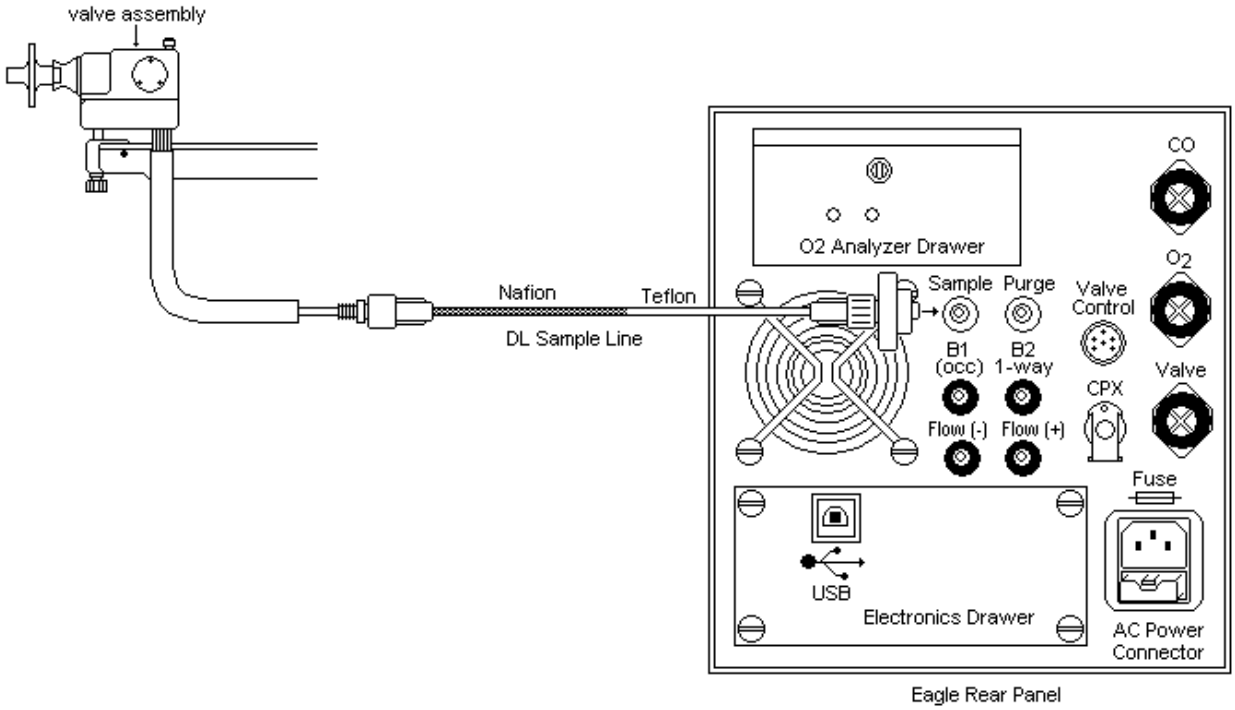


Figure 2-3. Connecting the DL Sample Line between the Eagle and Valve Tubing

Replacing the O_2 Analyzer

Frequency: As needed

1. On the Eagle rear panel, you will see a small drawer with a thumbscrew at the top (see O_2 analyzer drawer, Figure 2-4). Turn the thumbscrew $^3/_4$ of a turn and open the drawer. You will see the O_2 analyzer, a cylindrically shaped object, resting in its cradle.

2. Remove the ribbon cable, the Luer fitting and the small tubing from the analyzer. Remove the analyzer from its cradle.

3. Replace the analyzer and reattach the cable, Luer fitting and small tubing.

4. Return the analyzer to its cradle and close the panel. Tighten the thumbscrew.

NOTE:
The analyzers must be open to room air for 24 hours prior to installation. Analyzer life is approximately 6 months.

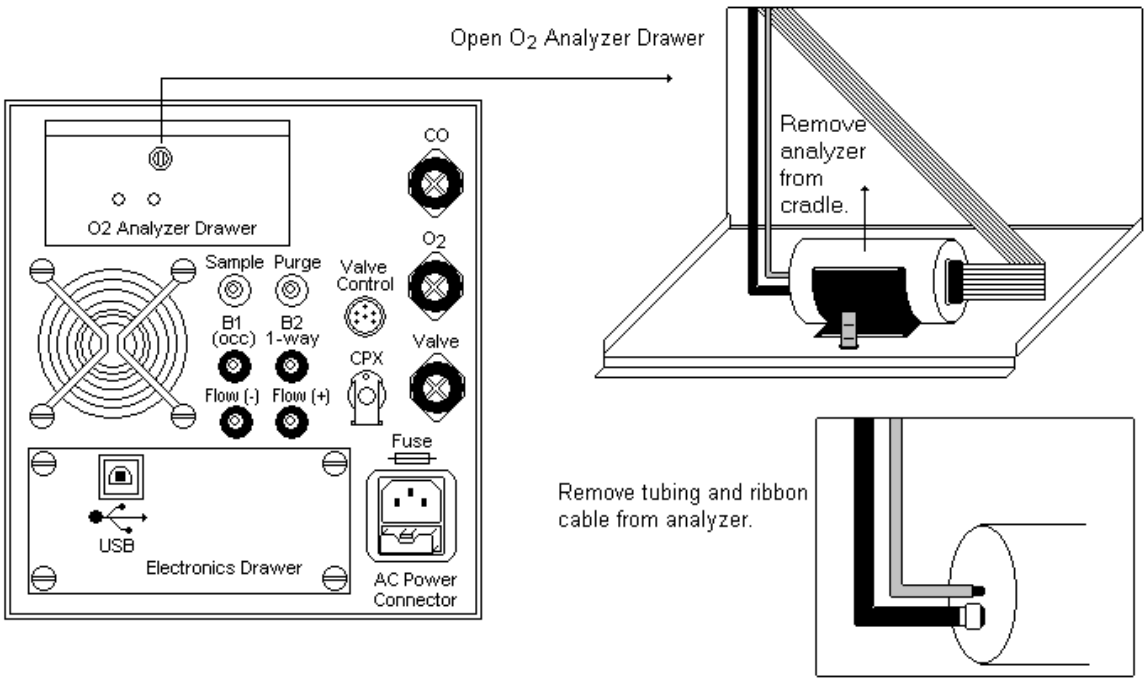


Figure 2-4. Replacing the O_2 Analyzer

Disinfection Procedure for Mouthpieces, Connectors, Couplers and Breathing Tubes

Frequency: After each Use

1. Following is a recommended procedure for disinfecting reusable mouthpieces, couplers/connectors and breathing tubes.

NOTE:
The following instructions involve the use of the disinfectant Cidex®. Only trained staff may use Cidex®. Wear gloves, goggles and an apron or gown. Avoid skin contact. The solution is caustic and can cause skin irritation.

2. Activate solution - solution turns green when activated.

3. Solution must be marked with the activation date and expiration date. Solution expires 14 days after activation.

4. Wash items thoroughly in detergent and water, then rinse prior to immersion in Cidex®.

6. Immerse in Cidex® for 20 minutes.

7. Remove from Cidex® using aseptic technique and rinse thoroughly with sterile water.

- Flush interior aspects vigorously with sterile water.
- Insertion tubes and channels must be thoroughly dried.

8. Discard Cidex® only after it has been neutralized.

Reference: Disinfection Instructions from *John Hopkins Cleaning and Disinfection* instructions at the following Website:

http://hopkins-heic.org/prevention/clean_dis.html

Cidex® Activated Dialdehyde Solution is a product of Advanced Sterilization Products.

Care of the Collins GEMtach

Frequency of cleaning: The Collins-supplied bacterial/viral filters designed to be used concurrently with the GEMtach (e.g., the DC2) significantly decrease downstream contamination. Therefore, under normal use, it is acceptable to clean the pneumotach at periodic intervals according to guidelines set by the hospital or laboratory's infection control committee. However, when contamination is believed to have occurred, such as with contagious patients, it is acceptable to clean the pneumotach after each patient. In addition, the pneumotach should be cleaned when the screen appears to be clogged with proteinaceous matter or other debris.

1. Remove the GEMtach from the breathing valve.

2. Immerse the GEMtach in the disinfectant solution as indicated under *Disinfection Procedure for Mouthpieces, Connectors, Couplers and Breathing Tube* in this section.

3. Soak the valve in the solution for the length of time recommended in the solution manufacturer's instructions. When you have completed the process, rinse the valve thoroughly according to the manufacturer's advice, again making sure to not get the tube fittings wet. Allow the whole valve to dry completely before reusing.

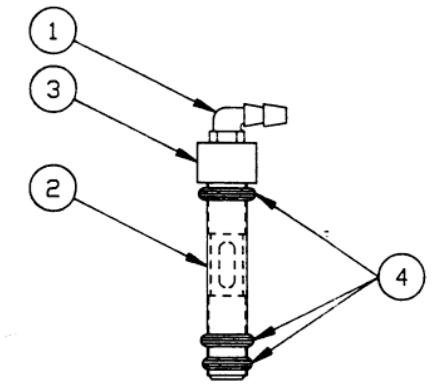
4. The GEMtach must be recalibrated after cleaning due to possible changes in flow dynamics.

Replacing the Balloon Cuffs in the Valve

Frequency: As needed

1. A leak in the system could indicate a leak in the valve, most likely, a leak in one of the two balloons. If a balloon cuff is damaged, it must be replaced.

2. Following is a drawing of the balloon core assembly to refer to when conducting the replacement procedure.



1. 1/8x10-32 R Angle Barb Fitting
2. Balloon Cuff
3. Balloon Core
4. #8 O-ring

Figure 2-5. Diagram of Balloon Core Assembly

3. Following are the items needed for replacing the Balloon cuffs:

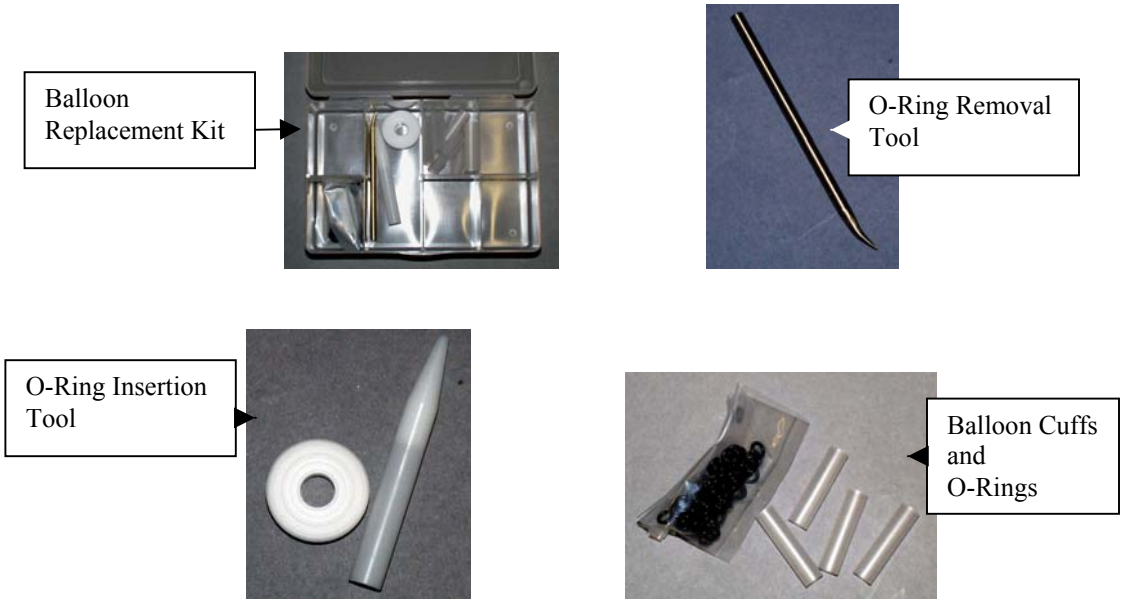


Figure 2-6. Items Needed for Replacing the Balloon Cuffs

4. Depressurize the valve by turning off the gas tanks.

5. To access the balloon assemblies, slide open the door at the top of the valve.

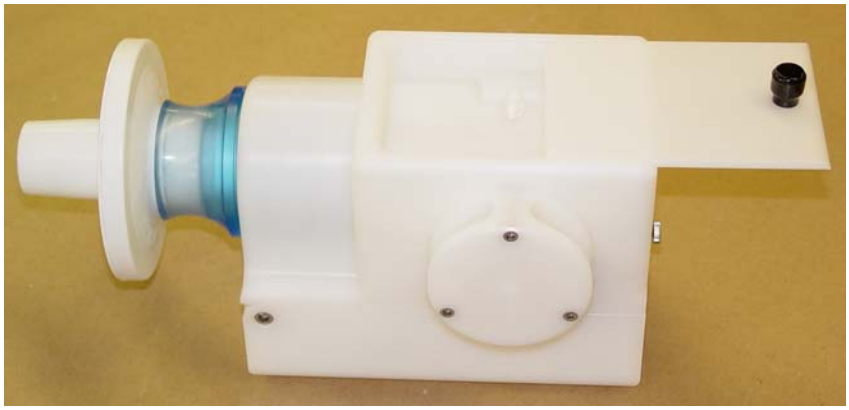


Figure 2-7. Sliding Open the Valve Door to Access the Balloons

6. Gently pull each balloon from its slot in the valve.

7. The balloon "cuff" is secured to the core assembly by three black O-rings. The O-rings and the balloon cuff will be discarded once removed. ***Do not reuse O-rings.***

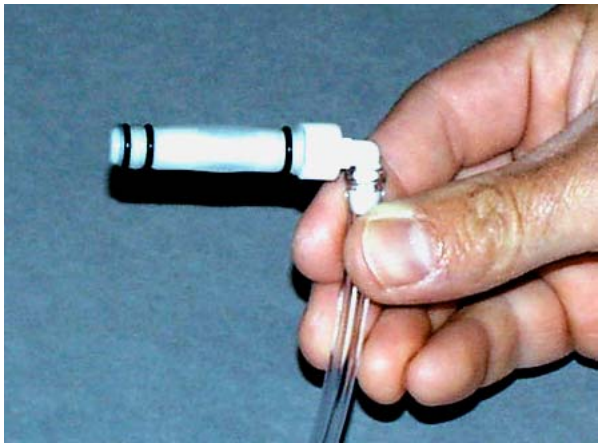


Figure 2-8. Location of O-Rings on the Balloon Cuffs

8. Using the *O-ring Removal Tool* provided, remove each O-ring. Hook the tool under each O-ring and pull it off. Once all O-rings have been removed, remove the balloon cuff from core assembly.

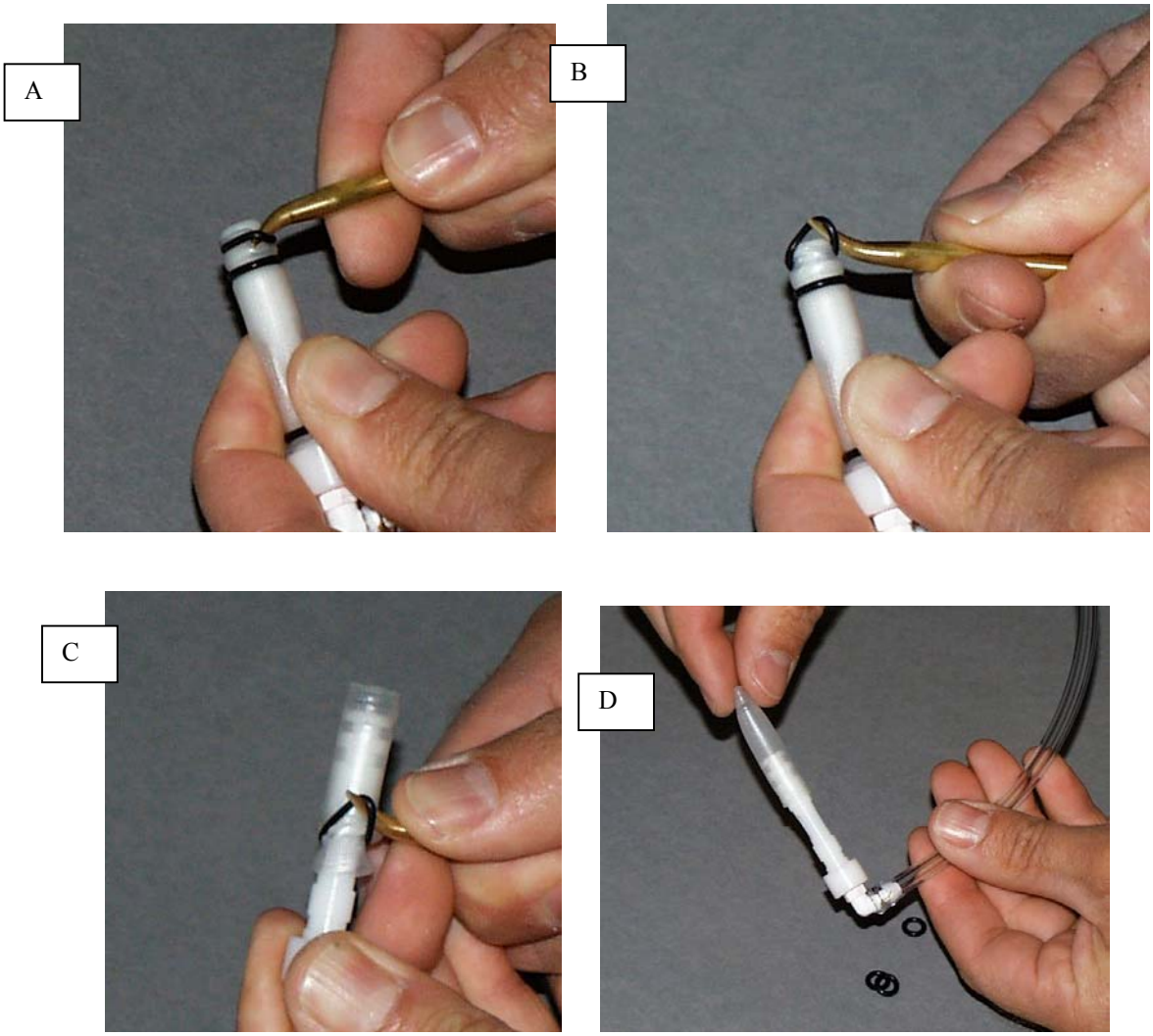


Figure 2-9. Removing the O-Rings

9. Install the new balloon cuff on the core assembly, *all the way to the shoulder*.

Figure 2-10. Installing the New Balloon Cuff on the Core Assembly

10. Install the O-rings using the *O-ring Insertion Tool* provided. First apply a light film of Super Lube® to the outside of the tool bar. Then start the O-ring up the tapered end of the bar. Using the tool collar, finish sliding the O-ring to the opposite end of the bar.

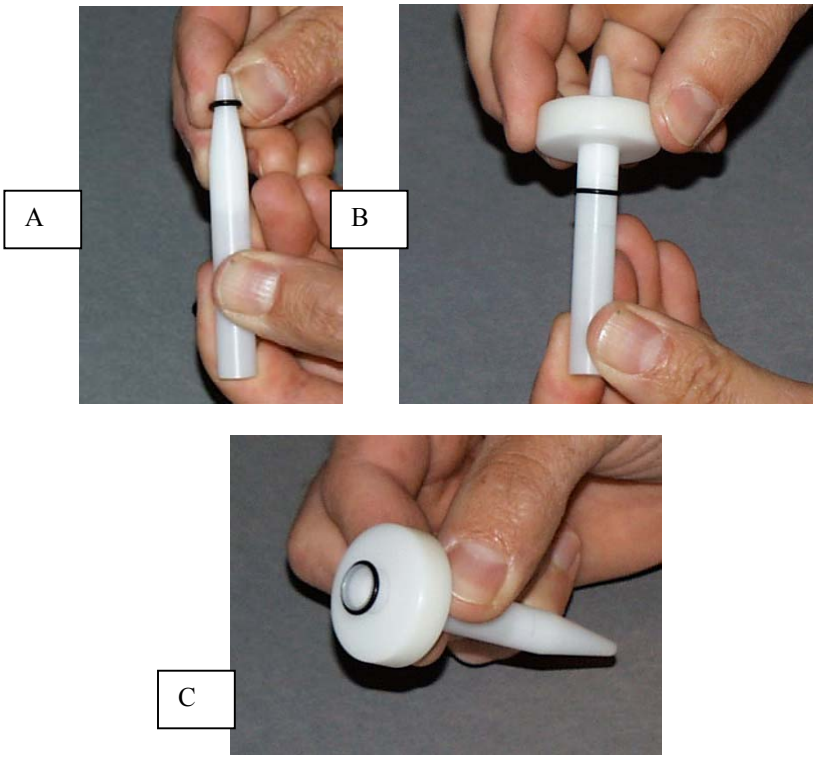


Figure 2-11. Sliding an O-Ring onto the Insertion Tool Bar

11. Slide the O-ring Insertion Tool over the balloon and core assembly. Line up the O-ring with the very beginning of the 3rd notch on the core assembly and slide the O-ring onto the notch to secure the balloon to the core.

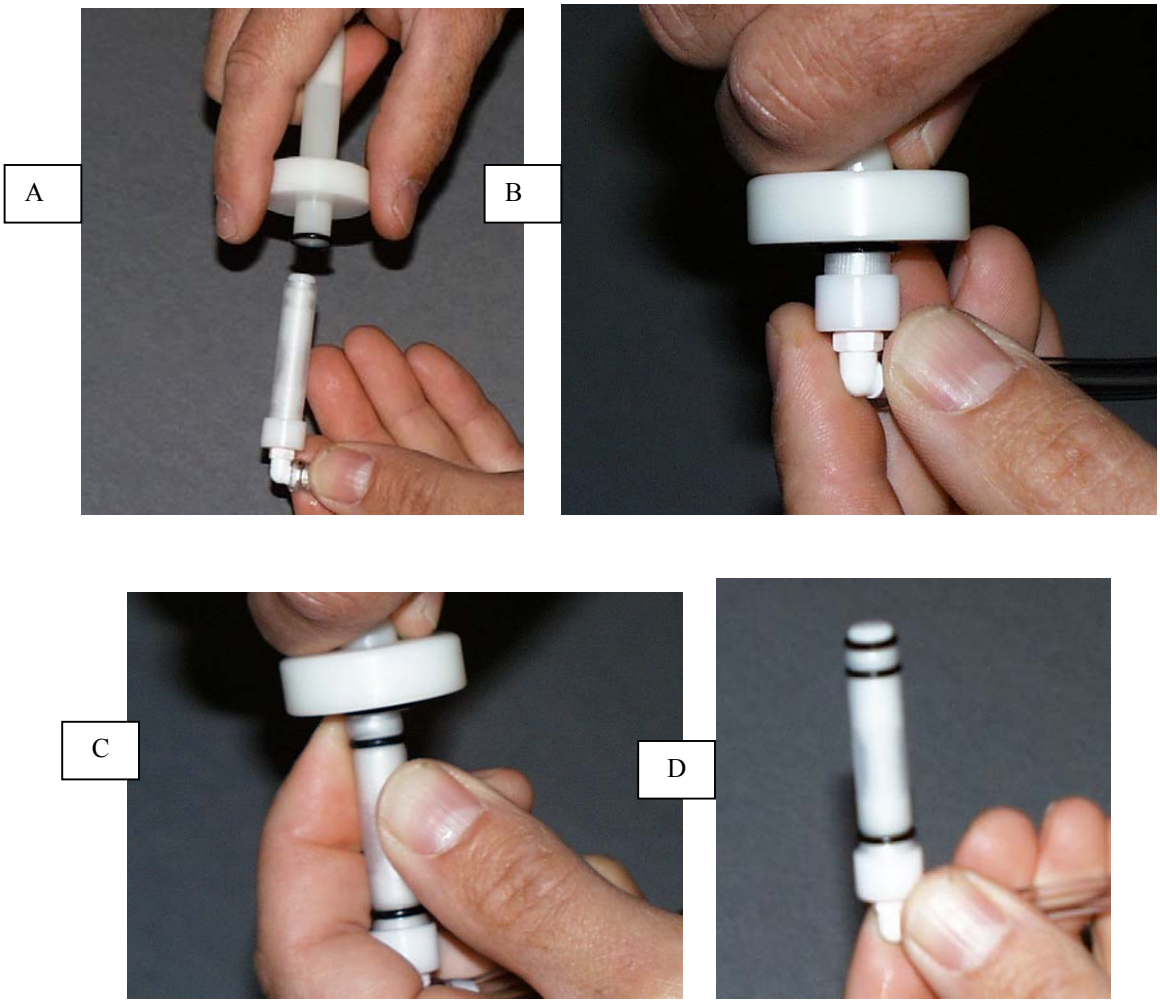


Figure 2-12. Installing the New O-Rings to Secure the Balloon to the Core Assembly

NOTE:
The O-ring Insertion Tool will not fit over installed O-rings. Work from farthest to closest.

12. Repeat the previous step for each O-ring.

13. Once all O-rings have been installed, apply a light film of Super Lube® to the outside of each O-ring and install the core assembly in the valve.

14. Before inserting each balloon, make sure that the attached tubing is pointing in the direction that it will go when the cover is replaced, that is, down through the cover slot. This is to avoid having to twist the balloons once they are seated.

15. Make sure that you do not scrape the balloon against the edge of the hole as you insert it, as this could weaken the material.

16. Insert the balloon all the way in the hole so that none of the black O-ring is showing outside the valve. If it does not go in all the way at first, keep pushing it until it does.

CAUTION:
Never twist the balloons!

Cleaning the Breathing Valve

Frequency: Monthly

1. To clean the valve, first depressurize the valve by turning off the gas tanks.

2. Remove the GEMtach and Demand Valve by pulling them out of the valve.

3. Remove the valve from the arm by lifting it off the arm post.

4. Cleaning the breathing valve involves cleaning just the top portion. Open up the valve at the hinge.

5. Inside the top portion of the valve you will see the red, green and white connections for the pneumotach and purge tubing. Undo these connections.

6. Slide open the door at the top of the valve.

7. Slide the balloons out from their slots inside the valve and gently pull the balloons and connected tubing from the valve. Leave the balloon assemblies resting on the bottom portion of the valve.

8. Unscrew the valve hinge using an Allen wrench.

Figure 2-13. Opening the Breathing Valve

9. The one-way valve on the side of the Breathing valve may also be removed using an Allen wrench and disassembled for cleaning.

10. Immerse the valve in the disinfectant solution as indicated under the *Disinfection Procedure for Mouthpieces, Connectors, Couplers and Breathing Tubes* in this section.

11. Soak the valve in the solution for the length of time recommended in the solution manufacturer's instructions. When you have completed the process, rinse the valve thoroughly according to the manufacturer's advice. Allow the whole valve to dry completely before reusing.

12. Reassemble the valve by reversing the above procedure.

13. Repressurize the valve by turning on the gas tanks.

Adjusting Regulator Valve Pressure

Frequency: As needed

1. The gas cylinder regulator valves are factory set at an outlet pressure of 50 psi. Although the regulators are factory set, over time they may need adjusting. This may be evidenced by difficulty in calibrating the gas analyzers. Follow the procedure below for making gas tank regulator adjustments.

2. Make adjustments to the gas cylinder regulators as described below, observing the following requirements:

   a. **All regulator adjustments must be done using a tank containing at least 1000 psi, as measured by the regulator gauge.** A full tank contains 2000 psi; therefore the tank must be at least half full.

   b. Make your adjustments and measure the pressure coming out of the valve with a pressure gauge. The pressure gauge should be graded fine enough to read 0-60 psi. Be sure to use a gauge that is labeled "Use No Oil".

3. Unscrew the hex cap from the end of the regulator body. You will see a hex-headed adjusting screw when the cap is removed. (If the cap on your regulator consists of an acorn nut, you will need a wrench to remove it.)

4. Disconnect the regulator tubing from the Eagle and attach the pressure gauge to the tubing.

5. Open the tank stem (counterclockwise). The regulator gauge should read at least 1000 psi.

6. Observe the reading on the pressure gauge. If it is not 50 psi, follow the steps below.

7. Close the tank stem.

8. Release the pressure in the gauge by removing the pressure gauge from the regulator tubing. Then reattach the pressure gauge to the tubing.

9. Insert a $^{3}/_{16}$" Allen wrench inside the hex adjusting screw. Turn the screw counterclockwise until it stops. This resets the diaphragm adjustment for 0 pressure.

10. Open the tank stem.

11. Slowly turn the screw clockwise until the pressure on the gauge measures 50 psi.

12. Close the tank stem again.

13. Release the pressure in the gauge by removing the pressure gauge from the tubing. Then reattach the pressure gauge to the tubing.

14. Open the tank stem once more to see that the gauge reads 50 psi. If it doesn't, make adjustments according to the steps above. When finished making adjustments, always check once more to see that the gauge reads 50 psi.

15. Close the tank stem. Reconnect the regulator tubing to the Eagle.

16. Replace the cap on the end of the regulator body.

17. Do the same for the other gas tanks if they also need adjusting.

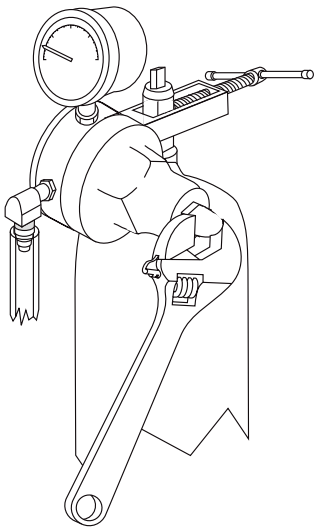


Figure 2-14. Removing the Cap from the Regulator Body

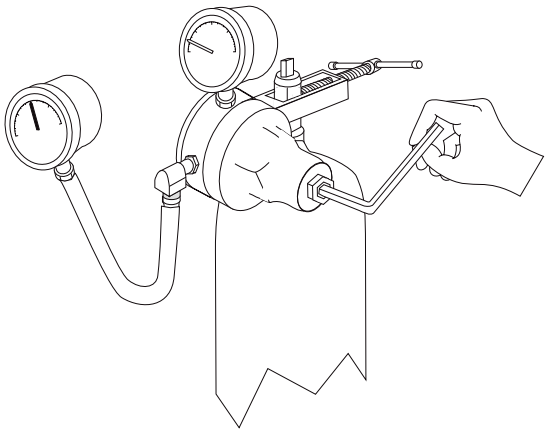


Figure 2-15. Adjusting Regulator Pressure with an Allen Wrench

SECTION THREE -- TROUBLESHOOTING

Description

This section is designed to help in the event that you encounter problems with your Eagle system. It consists of two parts:

- A Troubleshooting Guide illustrating some common error sources
- A User Problem Checklist, designed to help you gather information which may be useful to our Customer Support Services personnel.

WARNING:
WHEN CHECKING AC POWER CONNECTIONS, CABLE CONNECTIONS BETWEEN SYSTEM COMPONENTS, OR FUSES, MAKE SURE THAT THE POWER TO ALL SYSTEM COMPONENTS IS OFF.

Contacting Customer Support

If you are having problems with your system that cannot be resolved, contact Collins Medical personnel at:

800-635-3200
or
781-843-0610 and ask for the Customer Support Services Department.

Manuals

Where the problem is likely to be with the computer, keyboard, monitor, or printer, refer to the manuals accompanying these components for troubleshooting advice. For example, if you are having problems with the print format, refer to the printer manual.

TROUBLESHOOTING GUIDE

Following are descriptions of some common error sources and the steps to take in remedying them.

WARNING:
WHEN CHECKING AC POWER CONNECTIONS, CABLE CONNECTIONS BETWEEN SYSTEM COMPONENTS, OR FUSES, MAKE SURE THAT THE POWER TO ALL SYSTEM COMPONENTS IS OFF.

Problem #1 – nothing displays on the monitor screen…

Nothing displays on the monitor screen, or the PLUS program fails to "boot up" when the computer is turned on.

Check to make sure that:

1. The power to the computer and the monitor is turned on.

2. All cable and AC power connections have been made as described in Section One. Check in particular the cable connections between the monitor and the computer and the AC power connections for each of these components.

3. There are no broken ribbon cables. Broken cables can cause a variety of problems and it is fairly unpredictable what these will be.

4. The components are plugged into functioning outlets. Test the outlets with a functioning lamp to make sure. For components with detachable power cords, see that the other end of each power cord is plugged into its respective component as well.

5. The monitor brightness and contrast controls are set sufficiently to allow the display to show up.

6. No diskettes are inserted into the floppy disk drive. If a diskette is inserted, the system will try to boot from the floppy drive instead of the hard disk. A *Non-system disk in drive A* error message will be displayed.

7. Try rebooting the system by pressing Ctrl/Alt/Del. If this does not work, turn the power to the system off for 30 seconds; then turn it back on.

8. Check to make sure the fuses, located at the rear of the Eagle unit next to the power switch, have not been blown. If they have blown, replace them. If upon replacing the fuses, they blow again, contact Collins Medical, Inc.

9. If all the situations above have been checked, refer to the documentation accompanying your computer.

Problem #2 – monitor display is completely white…

When you turn on the power to the system, the monitor display is completely white and remains so throughout the computer boot-up procedure.

Check to make sure that:

1. The computer power switch is on, as the above situation occurs when the power to the monitor is on, but the computer power is not on.

2. The cable connections between the monitor and the computer are made as described in Section One and there are no broken ribbon cables.

3. The computer power cord is plugged into a functioning outlet.

4. Refer to the documentation accompanying your monitor for further details on determining monitor problems.

Problem #3 – monitor displays a message such as *Communication Error*…

The monitor displays a message such as *Communication Error*. This is an indication that the computer and the Eagle are not communicating. If such a message were to display, it would be most typically when initiating testing or calibration. Check to make sure that:

1. All power cord connections have been made as described in Section One and that the power to all system components is on.

2. The cable connection between the computer and the Eagle is made as described in Section One and there are no broken cables.

3. The fuses are not blown (refer to problem #1).

4. If any of the problems listed above exist, first remedy the situation and then reboot the system by pressing Escape to get to the Main Menu and following the Windows Shutdown procedure.

5. If the problem is not due to any of the above situations, try rebooting the system by pressing Escape to get to the Main Menu and following the Windows Shutdown procedure. If this does not work, power down the system for 10 seconds and power up again, as electrical disturbances, commonly known as "spikes", can cause occasional malfunction of electrical components.

Problem #4 – unable to perform testing or calibration operations…

You are unable to perform testing or calibration operations because the Eagle does not respond to user-keyboard action.

1. Make sure the gas tanks, which run the valve, are turned on. If they are not on, the valve will not function.

2. Check for the proper tubing and sample line attachments.

3. Make sure the monitor brightness and contrast controls are set sufficiently to allow the entire display to show up. Otherwise a prompt which requires a response in order for the program to continue may not be visible.

4. Check all cable and power cord connections, and power switches. Make sure there are no broken cables. Check the fuses, as described in Problem #1.

5. Try to isolate the problem by finding out which components are not responding. If a particular component does not function, the problem may be isolated to that component. If none of the components respond, then there is most likely a communication problem.

6. If the problem occurs during a test procedure, make sure the patient is breathing through the GEMtach. Otherwise, in some cases, the system will not see flow and the program will not proceed.

7. If the problem persists, reboot the system by exiting to the Desktop and following the Windows Shutdown procedure. If this does not work, reset the power to the system by turning it off for 10 seconds and then on again, as electrical noise may have been the source of the problem.

8. If the source of the problem cannot be located, contact your Collins Service Representative.

Problem #5 – unable to attain a satisfactory calibration…

You are unable to attain a satisfactory calibration, i.e., you can't get it to Pass.

1. Repeat calibration, making sure that the entire procedure is performed correctly.

2. If results are still out of range, contact your Collins Customer Support Services Representative.

3. If you are having problems with GEMtach calibration, see the next problem.

Problem #6 – unable to attain a satisfactory Pneumotach (GEMtach) calibration…

You are unable to attain a satisfactory Pneumotach (GEMtach) calibration; i.e., you can't get all parameters to Pass.

1. In the section about pneumotach calibration, read about the error messages you will get if you do not conduct the procedure correctly.

2. Repeat Calibration, making sure that the entire procedure is performed correctly. If problems still occur, proceed to the next step.

3. Make sure that the GEMtach is clean and undamaged. Check in particular the screen to make sure it isn't dirty. If the GEMtach needs cleaning, proceed with the appropriate instructions in the Maintenance section of this manual.

4. After remedying the possible source of difficulty, repeat the calibration procedure. If none of these steps results in successful calibration, contact your Collins Customer Support Services representative.

Problem #7 – problems calibrating the analyzers…

You are having problems calibrating the analyzers. Most problems with analyzer calibration are procedural and are therefore easily remedied. If the calibration values are out of range or if any other problems exist, follow these steps:

1. Repeat calibration, making sure that the entire procedure has been performed correctly. If problems still occur, proceed to the next step.

   Make sure of the following:

2. That the gas tanks are turned on and that there is sufficient gas and pressure in each tank and in the sample lines leading from them. If all of the above situations check out, the gas tank regulators may need adjusting. This would more likely be the case if you had your system for a long period of time. Refer to *Adjusting Regulator Valve Pressure* under Maintenance for more details.

3. That all gas tank tubing connections are correct and secure.

4. That the sample line is not bent or crimped.

5. That the system has been allowed to warm up for 15 minutes after power-up before performing calibration.

6. Analyzer response and delay failures may indicate a problem with the sample line. Sample lines need to be replaced every 3 to 4 months.

7. After remedying the source of difficulty, repeat the calibration procedure. If none of these steps results in successful calibration, contact your Collins Service Representative.

Problem #8 – test results appear unreasonable…

Test results appear unreasonable, i.e., they are either much higher or much lower than expected.

1. Make sure that the system is calibrated properly. The gas analyzers should be calibrated and the GEMtach should be verified prior to each test. Additionally, GEMtach calibration should be performed under the following circumstances:

   a. The first time the PLUS program is run.
   b. Each day before conducting tests.
   c. Each time a new version of the PLUS program is installed.
   d. After cleaning or replacing the GEMtach.
   f. After replacing the sample line.

2. Conduct a Verify procedure with the GEMtach to see that it is measuring correctly. If it is not, repeat calibration, making sure that the entire procedure is performed correctly.

3. Be sure the appropriate calibration is conducted prior to testing, that is, GEMtach calibration prior to the FVC test and analyzer calibrations prior to DSB testing.

   Check to see that:

4. The proper tubing is connected and that there are no leaks in the system. Make sure the tubing between the Valve and the Eagle is matched up correctly. If the positive (+) and negative (-) flow tubes are reversed, expired flow will be read as inspired flow and vice versa. Refer to the *Installation* procedure in Section One for the correct way to attach the tubing.

5. The GEMtach is clean and undamaged. Refer to Maintenance for instructions on cleaning the GEMtach. If it is damaged, replace it.

6. The patient was wearing a noseclip and he was making a tight seal around the mouthpiece.

7. Setup was correct prior to testing, e.g., gas valves were on, etc..

8. The test was started properly.
9. The test was ended properly.
10. The correct keys were pressed for each operation.
11. The correct preliminary and patient data were entered.
12. The patient performed the test correctly.
13. The correct patient age, height and gender were entered. Otherwise, percentage of predicted results may be distorted.

Problem #9 – Printer does not respond…

The printer does not respond when a printout is initiated from the keyboard.

Check to see that:

1. The power to the printer is turned on.

2. The printer is in the on-line mode.

3. The printer AC power cord is plugged into an appropriate outlet.

4. The cable connections between the printer and the Computer are made as indicated in Section One.

5. Make sure that the printer is configured for the correct print functions. Refer to your printer manual for how to set these functions.

6. Refer to the printer manual for more details on printer malfunction.

Problem #10 – pressing End or Arrow keys on numeric pad produces numerical data…

Pressing the End key or the Arrow keys on the numeric pad produces numerical data on the screen instead of the desired action.

If this is the case, most likely the Num Lock key has been pressed inadvertently, thereby activating the numeric functions of these keys. To rectify this situation, press the Num Lock key. The non-numeric functions of these keys will thus be restored.

Problem #11 – communications error during DL calibration…

You receive the following type of message during the DL test or calibration:

MG COMMUNICATIONS ERROR

If you receive this message, exit the testing or calibration module and re-enter. If this fails, reboot the system. If the problem still is not solved, call the Customer Support Department at 800-635-3200.

Problem #12 – quick disconnect end of gas tank regulator tubing keeps popping off…

The quick-disconnect end of the gas tank regulator tubing keeps popping off.

1. Trim the end of the tubing for a tighter fit.

2. Check the regulator valve pressure and adjust if necessary.

NOTE:

Do NOT secure the end of the Tygon tubing attached to the Luer-lock fittings with tie wraps or any other type of clamp. If the pressure does increase, it is preferable to have the

tubing pop off on the outside, where it is accessible. If the tubing were to be clamped, the pressure buildup could cause the tubing to pop off internally, making it very difficult to locate. Instead, follow the steps given above.

Isolating the Problem - a General Guide

1. If you encounter a problem that does not fit one of the scenarios just described, it is helpful to at least be able to determine whether the problem is with your computer or with the Eagle unit.

2. If you are having problems with a particular component on the Eagle, such as the pump, most likely the problem is with the Eagle hardware associated with this component. However, if none of the Eagle components work, and all power cords are plugged in, power switches are turned on, cables are secure, and fuses are intact, then most likely the situation is a communication problem between the Eagle and the computer. Contact your Collins Service Representative for assistance.

3. If you receive a communication error on the monitor screen, most likely the problem is between the Eagle and the computer. Check all cable, power cord connections, power switches, and the fuses as previously described.

4. Once you have isolated the general location of the problem, you can then refer to the appropriate scenario in the Troubleshooting Guide. If the problem still cannot be found, communicate all the information gathered to your Collins Customer Support Services Representative.

6. For some problems where test data is not threatened, it may be helpful to reboot the system. If this does not work, power down the system for 10 seconds and then power up again, as electrical noise may be the source of the trouble.

User Problem Checklist

1. If a user suspects there is a problem with the Eagle system, first determine:

   a. Is the problem reproducible? Repeat the test/calibration steps to see if the same problem reoccurs.
   a. Is it a fault within the system or is it a problem with the patient or a test procedure?
   b. Is the test being conducted as described in the instruction manual?
   c. Is the system set up as described in the PLUS and the Eagle manuals?

2. Then, define the problem as specifically as possible. For example:

   a. Are the test results inaccurate? Which test? Are the results greatly exaggerated?
   b. Does the system have any leaks?
   c. Is the problem electrical in nature? (Circuitry, lights, computer, power cords, etc.)

WARNING:

If you get water on or near the electrical circuitry, power down the system immediately and unplug all AC power cords from their outlets. Do not reapply power until all water or moisture is completely eliminated. Contact Collins Medical, Inc. if necessary.

   d. Is the problem mechanical in nature? (printer problems, monitor problems, valve problems, etc.)
   e. Is the problem in the pulmonary software? (The Collins-supplied Program Disks.) Was the program loaded correctly?
   f. Were the questions in the Configuration program, especially the hardware section, answered correctly?

3. Next, perform the following simple system checks:

   a. Is the electrical power to the system turned on?
   b. Are all system component power switches turned on?
   c. Are any fuses blown? Are there any loose connections?
   d. Is the proper tubing connected? Does any of the tubing leak?
   e. Was the system set up properly before testing began?

f. Did the test start properly, according to the manual?
g. Did the test end properly, according to the manual?
h. Was the correct patient data entered? Was the data entered into the computer properly?
i. Was the wrong key pressed?
j. Did the patient perform the test exactly as instructed?
k. Did the operator perform the test as described in the manual?
l. Was the system calibrated correctly?
m. Is there any clue as to why the test results are inaccurate? (Recent calibration or maintenance, for example.)
n. Were there any changes to the system since the last test was conducted?

4. Now, list all possible details relating to the suspected problem, including but not limited to:

a. Temperature, barometric pressure of the testing room (especially for areas at altitude.)
b. Patient's height, weight, age, sex, race.

NOTE:

Beware of misassigning height or weight units, as this will cause inappropriate predicted values to be calculated. Let's say, for example, that in the Patient Information program, you were to enter a height of 66 in the *centimeters* box whereas you had intended to enter it in the *inches* box. The program would interpret the height to be 66 centimeters and the predicted values would be incorrect.

c. Type of test in question, if known. (Save a printed copy.)
d. Any modifications, maintenance, or calibration performed on the system since the last correct test results were obtained.
e. All calculations performed, if available (Attempt to manually calculate the test results to compare with the suspected inaccurate computer-provided results).
f. The exact sequence of steps that led to the problem. Can you cause the event to occur repeatedly? Make a note of the exact procedure used, including keystrokes and handling of the equipment.
g. All miscellaneous aspects of the suspected problem.

5. If the source of the problem is found:

a. Can it be fixed without outside help?
b. Is enough information available to discuss the problem over the telephone with a service representative?
c. Is an on-site visit from a service representative necessary? (If in doubt, call Collins Medical on the telephone first.)

6. Finally, if the source of the problem cannot be determined:

a. Is all possible information about the problem written down and available? Could someone else understand this information if the usual operator were not available?
b. Is enough information available to precisely describe the problem over the telephone to a service representative?
c. Is all relevant information written down legibly for a service representative to evaluate on-site?
d. Has everything been double-checked?

7. When calling Collins Medical, Inc. for Service or Technical Support (Phone 800-635-3200)

a. Identify the type of system you have. Make sure you know the following:

Your Customer Number
The type of computer in your system
The program name (e.g., PLUS) and version (e.g., PLUS 2000, ver. 4.5). To find the version number, click on *Help*, then *About*….
The serial number of your Eagle

b. Have all information regarding the problem. Let the technician know the error messages you are getting and when they occur, if applicable. Describe what you were doing when the error occurred and the steps you have taken to attempt to solve the problem.

c. Call from a telephone at or near your computer. You may be asked to type some commands at the keyboard, or make minor adjustments, relay detailed information during operations, or try other troubleshooting steps at the system itself.

d. For all third party software, such as Lotus 1.2.3, QuattroPro, Excel for Windows, etc., contact the manufacturer of that particular software for troubleshooting advice.

Supplies Listing - Accessories and Disposable Items

For more information, refer to our website at www.collinsmedical.com.

Supply # Item Name

700964 GEMtach
022380 Bronchial Challenge Kit (5 Nebulizers)
021156 Calibration Syringe, 3-liter
381248 DLCO Replacement Nafion Tubing

Filters and Mouthpieces
022450 DC-2 Filter
022452, box of 24
022454, box of 100
022456, box of 400
022458 DC-2 Filter and Disposable Comfort Fit Mouthpiece
022460, box of 24
022462, box of 100
022464, box of 400
022465 Disposable PFT Kit, includes, DC-2 Filter, ComfortFit Mouthpiece and Soft Noseclip, box of 100
022242 Disposable Comfort-fit Mouthpiece
02240x Disposable Cardboard Mouthpieces
021231 Disposable Soft Noseclip

Gasses
022663 Rapid-Response DLCO Gas Mixture in Disposable E-Cylinder
022600 Oxygen in Disposable E-Cylinder
022681 CPX Span Gas in Disposable E-Cylinder
022919 Circular Hand Wrench for Opening Gas Tanks

References

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American Journal of Respiratory and
Critical Care Medicine, Vol 152, No.6,
pp. 2188 -2189, December 1995.

2. (AARC guidelines for infection control)
AARC Clinical Practice Guideline - Spirometry,
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Vol 41, No. 7, pp. 629-636, 1996.

Basic Theory of the Eagle

1. The Collins Eagle system consists of instrumentation for performing pulmonary function testing, specifically, FVC, MVV, Lung Volumes and Diffusion Capacity.

2. Following are some major components of the Eagle.

   Breathing Valve: Automates a variety of pulmonary function test procedures.

   Demand Valve: Opens and closes to allow the patient to breathe the appropriate test gasses as directed by the software.

   GEMtach: Allows pneumotach-based spirometry with the Eagle. Measures flow directly and integrates flow to arrive at volume measurements.

   microGA Multiple Channel Analyzer: This analyzer measures the amount of CO_2, CO, and CH_4 in each patient breath or in the calibration gas during Diffusion testing.

   O_2 analyzer: For determining lung volumes via the N_2 washout method.

Spirometry

Typically, a pulmonary function system is equipped with either a pneumotach or a spirometer, or both.
In the Collins Eagle system, spirometry measurements are made with the use of the Collins GEMtach, which is a pneumotach. The patient breathes through the GEMtach, which is a device that measures flow across a flow-resistive element, in this case, the GEMtach screen. The inspired or expired flow reading is then integrated into a volume reading with the aid of a computer.

Lung Volumes

Several key lung volumes are defined below. Refer to Figure 3-1 for a diagram of lung volumes and capacities.

Tidal Volume (TV): The volume of air breathed in or out of the lungs during normal breathing.

Functional Residual Capacity (FRC): The volume of air left in the lungs at the end of expiration during normal breathing.

FRC is composed of the following two volumes:

The **Expiratory Reserve Volume (ERV):** the maximal additional volume of air that can be exhaled following a normal expiration to FRC.

The **Residual Volume (RV):** the volume of air remaining in the lungs at the end of a maximal exhalation.

Vital Capacity or Slow Vital Capacity is the maximum volume of air expired from the point of maximum inspiration without attention to speed. However, a maximal effort is still required through the end -expiration.

Total Lung Capacity is the maximal amount of air the lungs can hold, including VC and RV. This is the lungs at their "total capacity" at the end of a maximal inspiration.

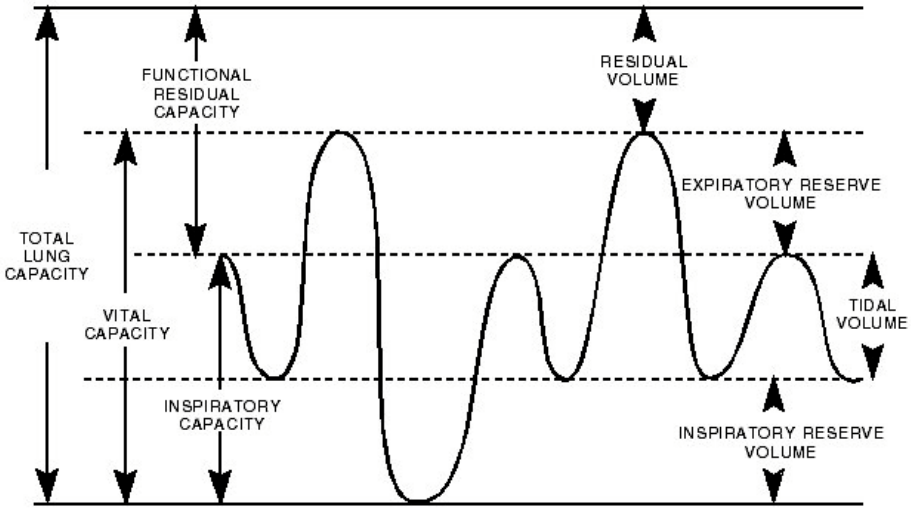

Figure 3-1. Lung Volumes and Capacities

While most lung volumes can be determined via direct spirometry, RV, FRC and TLC cannot be measured via direct spirometry. In the Eagle, these measurements are obtained by using the gas dilution technique, N_2 washout.

Gas dilution techniques for determining lung volumes are based on a single proportional relationship. This relationship is expressed in the following equation, where C is gas concentration and V is volume.

$$C_1V_1 = C_2V_2$$

This states that the product of gas concentration and volume stays constant. In other words, for a given amount of gas, as the gas concentration increases, the volume decreases and vice versa. With gas dilution methods, analyzers measure the gas concentrations at the beginning and the end of a study, thus providing C_1 and C_2. If one volume is known (the system volume or the volume exhaled by the patient), the unknown volume (the desired lung volume) can be solved for in the equation as follows:

$$V_1 = \frac{C_2V_2}{C_1}$$

In the Nitrogen washout technique, the natural volume of nitrogen in the patient's lungs is washed out and diluted with 100% O_2. With a normal breathing pattern beginning at FRC, the patient breathes in 100% O_2 from the gas tank and expires to room air. The N_2 is measured at the beginning and the end of the maneuver and the volume exhaled from the patient's lungs is measured by the GEMtach. In this way the unknown volume, FRC, can be solved for in the equation.

Diffusing Capacity

Diffusing capacity of the lung is a measure of the lung's ability to diffuse O_2 from the alveoli to the capillary blood and CO_2 from the capillary blood to the lung to be expired and removed from the body. Diffusing capacity is reduced when alveolar walls are destroyed and pulmonary capillaries are obliterated by emphysema and when the alveolar-capillary membrane is thickened by edema, consolidation, or fibrosis. The method used by the DL module to determine diffusing capacity of the lungs involves the use of carbon monoxide (CO), since it has diffusing characteristics similar to those of O_2 and because of the great affinity of hemoglobin for CO. There are several methods available for measuring the diffusing capacity of the lung for CO (DL_{CO}). The Collins DL module uses the single-breath method. In this method, the patient takes in a very low concentration of CO in a single inspiration and follows this by a 10-second breath-holding period. He then exhales and the expired fraction of CO is measured using an infrared CO analyzer, the concentration of gas in the lungs is determined via the dilution of CH_4 during the single breath maneuver, and the rate of carbon monoxide uptake from the lung is calculated by the software.

In the Collins Eagle system, the microGA Rapid Response Analyzer method of measuring gas fractions during lung diffusion testing has eliminated the alveolar bag previously used for sample collection in the conventional diffusion method. With the microGA method, methane (CH_4) is used in place of helium as a tracer gas. A tracing of gas concentrations during the maneuver is displayed along with the volume tracing, thereby allowing the user to determine where washout occurred and sample collection began. Using the microGA analyzer increases the accuracy of gas measurements and allows the user to visualize the point where washout is complete. The same equations are used for determining DLSB as for the conventional method; however, CH_4 is substituted for He.

The sample analyzed to determine DLCO is collected from the stored realtime data. Washout, sample volume, and sample window position can be modified anytime the patient's data is reviewed.

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